

Licence Application

Tracking Number:	MI-2021-LI-10110-1	Application Source:	Applicant
Status:	Under Review	Inspection File Numbers:	
Original, Tracking Number	MI-2019-LI-01002-1	File Numbers:	Site: PH19/50654 Lic & Cer: E19-518787 Inspection: PH19/50656 App. Review: E19-518790 Variation: E21-387698
Licence Version Number:	3	Expiry Date:	31/12/2030
Issue Date:	15/04/2020	Next Renewal Date:	01/10/2022
Last Renewal Date:	22/09/2021		
Conditions:	This licence does not authorise the manufacture of medicines listed for export that include substances at a level only permitted in medicines contained within schedules 2, 3, 4 & 8 of the Poisons Standard.		

Client Details

Applicant

Applicant Name:	GMP Pharmaceuticals Pty Limited		
Client ID:	29989		
Address:	7-9 Amax Avenue		
Suburb:	GIRRAWEEEN	State:	NSW
Post code:	2145	Country:	Australia

Manufacturer

Manufacturer Name:	GMP Pharmaceuticals Pty Limited	Client ID:	29989
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Manufacturer details

Proposed Manufacturer Name:	GMP Pharmaceuticals Pty Limited
Proposed Manufacturer Site Details:	

Billing Address

Address:	7-9 Amax Avenue		
Suburb:	GIRRAWEEEN	State:	NSW
Postcode:	2145	Country:	Australia

Primary Site

Activities to be undertaken at the licence site(s):	Medicine - API & Sunscreens
Licence variation type:	Variation of manufacturing site authorisation
Is this application for the collection of fresh blood components?	No

Site

Street Address:	60 Huntingwood Drive		
Suburb:	HUNTINGWOOD	State:	NSW

Post Code:

s22

Contact Name:

Country: Australia

Email:

Phone:

s22

Mobile:

Person in charge of Quality Control:

Person in charge of Production:

Authorised Person for Release:

No	Manufacturing Type	Sterility	Manufacturing Class	Dosage Form	Product Code	Manufacturing Step
1	Medicine manufacture	Non Sterile	Not Applicable	All Dosage Forms	Listed Therapeutic Good	Storage
2	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Tablet, orally disintegrating	Listed Therapeutic Good	Finished Product Manufacture
3	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Tablet, chewable	Listed Therapeutic Good	Finished Product Manufacture
4	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Tablet, uncoated	Listed Therapeutic Good	Finished Product Manufacture
5	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Powder	Listed Therapeutic Good	Finished Product Manufacture
6	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Capsule, enteric	Listed Therapeutic Good	Finished Product Manufacture
7	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Capsule, hard	Listed Therapeutic Good	Finished Product Manufacture
8	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Capsule, modified release	Listed Therapeutic Good	Finished Product Manufacture
9	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Tablet, effervescent	Listed Therapeutic Good	Finished Product Manufacture
10	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Tablet, film coated	Listed Therapeutic Good	Finished Product Manufacture
11	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Tablet, enteric coated	Listed Therapeutic Good	Finished Product Manufacture
12	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Tablet, modified release	Listed Therapeutic Good	Finished Product Manufacture

13	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Granules	Listed Therapeutic Good	Finished Product Manufacture
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Secondary Site

Supporting Documents

An electronic copy of your Site Master File, Quality Manual or Technical Master File MUST support this application or it will not be valid. However you may also provide a hardcopy of the files if an electronic one is not available.

Electronic Document List

Paper Document List

No	Document Type	Description	Method	Date

Fees and Payment

Fees and Payment

Fees: AUD \$820.00

Payment Type:

Reports

Report Requested

No.	Date Requested	Report Type	Date Sent
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Report Received

No.	Date Received	Report Type
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Type Of Change

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Original, Tracking Number	MI-2019-LI-01002-1	File Numbers:	Site: PH19/50654 Lic & Cer: E19-518787 Inspection: PH21/4608 App. Review: E21-407633 Variation: E21-387698
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Proposed Manufacturer Name:	GMP Pharmaceuticals Pty Limited
Proposed Manufacturer Site Details:	

Billing Address

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Suburb:	GIRRAWEEEN	State:	NSW
Postcode:	2145	Country:	Australia

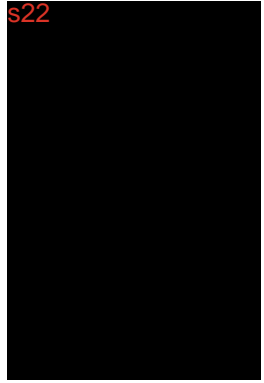
Primary Site

Activities to be undertaken at the licence site(s):	Medicine - API & Sunscreens
Licence variation type:	Variation of manufacturing site authorisation
Is this application for the collection of fresh blood components?	No

Site

Street Address:	60 Huntingwood Drive		
Suburb:	HUNTINGWOOD	State:	NSW

Post Code:
 Contact Name:
 Email:
 Mobile:
 Person in charge of Quality Control:
 Person in charge of Production:
 Authorised Person for Release:



Country: Australia
 Phone:



No	Manufacturing Type	Sterility	Manufacturing Class	Dosage Form	Product Code	Manufacturing Step
1	Medicine manufacture	Non Sterile	Not Applicable	All Dosage Forms	Listed Therapeutic Good	Storage
2	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	All Dosage Forms	Listed Therapeutic Good	Testing
3	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Powders and Granules Group	Listed Therapeutic Good	Finished Product Manufacture
4	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Solid Unit Dosage Forms - Tablets	Listed Therapeutic Good	Finished Product Manufacture
5	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Capsule, hard	Listed Therapeutic Good	Finished Product Manufacture

Secondary Site

Supporting Documents

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Fees and Payment

Fees and Payment

Fees: AUD \$820.00

Payment Type:

Reports

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Licence Application

Tracking Number:	MI-2021-LI-10110-1	Application Source:	Applicant
Status:	Under Review	Inspection File Numbers:	
Original, Tracking Number	MI-2019-LI-01002-1	File Numbers:	Site: PH19/50654 Lic & Cer: E19-518787 Inspection: PH21/4608 App. Review: E21-407633 Variation: E21-387698
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Manufacturer Name:	GMP Pharmaceuticals Pty Limited	Client ID:	29989
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Manufacturer details

Proposed Manufacturer Name:	GMP Pharmaceuticals Pty Limited
Proposed Manufacturer Site Details:	

Billing Address

Address:	7-9 Amax Avenue		
Suburb:	GIRRAWEEEN	State:	NSW
Postcode:	2145	Country:	Australia

Primary Site

Activities to be undertaken at the licence site(s):	Medicine - API & Sunscreens
Licence variation type:	Variation of manufacturing site authorisation
Is this application for the collection of fresh blood components?	No

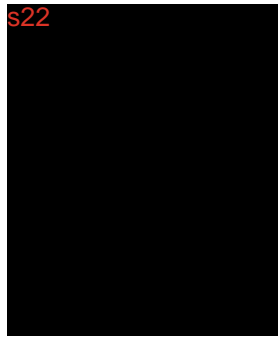
Site

Street Address:	60 Huntingwood Drive		
Suburb:	HUNTINGWOOD	State:	NSW

Post Code: 2148

Country: Australia

Contact Name:



Phone:

Email:

Mobile:

Person in charge of Quality Control:

Person in charge of Production:

Authorised Person for Release:

No	Manufacturing Type	Sterility	Manufacturing Class	Dosage Form	Product Code	Manufacturing Step
1	Medicine manufacture	Non Sterile	Not Applicable	All Dosage Forms	Listed Therapeutic Good	Storage
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3	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Powders Group	Listed Therapeutic Good	Finished Product Manufacture
4	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Granules Group	Listed Therapeutic Good	Finished Product Manufacture
5	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Solid Unit Dosage Forms - Tablets	Listed Therapeutic Good	Finished Product Manufacture
6	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Capsule, hard	Listed Therapeutic Good	Finished Product Manufacture

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Fees and Payment

Fees: AUD \$820.00

Payment Type:

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Report Requested

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Report Received

No.	Date Received	Report Type
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Type Of Change

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Type of Change:

Licence Application

Tracking Number:	MI-2019-LI-01002-1	Inspection File Numbers:	
Status:	Active	File Numbers:	Site: PH19/50654 Lic & Cer: E19-518787 Inspection: PH19/50656 App. Review: E19-518790
Original, Tracking Number	MI-2020-LI-13501-1	Expiry Date:	31/12/2030
Licence Version Number:	3	Next Renewal Date:	01/10/2022
Issue Date:	15/04/2020		
Last Renewal Date:	22/09/2021		
Conditions:	This licence does not authorise the manufacture of medicines listed for export that include substances at a level only permitted in medicines contained within schedules 2, 3, 4 & 8 of the Poisons Standard.		

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Client ID:	29989		
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Suburb:	GIRRAWEEEN	State:	NSW
Post code:	2145	Country:	Australia

Manufacturer

Manufacturer Name:	GMP Pharmaceuticals Pty Limited	Client ID:	29989
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Billing Address

Address:	7-9 Amax Avenue		
Suburb:	GIRRAWEEEN	State:	NSW
Postcode:	2145	Country:	Australia

Primary Site

Activities to be undertaken at the licence site(s):	Medicine - API & Sunscreens
Is this application for the collection of fresh blood components?	No

Site

Street Address:	60 Huntingwood Drive		
Suburb:	HUNTINGWOOD	State:	NSW
Post Code:	2148	Country:	Australia
Contact Name:	s22	Phone:	s22
Email:	[REDACTED]		
Mobile:	[REDACTED]		
Person in charge of Quality	[REDACTED]		

Control: s22

Person in charge of Production: s22
1.Please refer to Trim container.docx

Authorised Person for Release: s22

No	Manufacturing Type	Sterility	Manufacturing Class	Dosage Form	Product Code	Manufacturing Step
1	Medicine manufacture	Non Sterile	Not Applicable	All Dosage Forms	Listed Therapeutic Good	Storage
2	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	All Dosage Forms	Listed Therapeutic Good	Testing
3	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Tablet, orally disintegrating	Listed Therapeutic Good	Finished Product Manufacture
4	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Tablet, chewable	Listed Therapeutic Good	Finished Product Manufacture
5	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Tablet, uncoated	Listed Therapeutic Good	Finished Product Manufacture
6	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Powder	Listed Therapeutic Good	Finished Product Manufacture

Secondary Site

Supporting Documents

An electronic copy of your Site Master File, Quality Manual or Technical Master File MUST support this application or it will not be valid. However you may also provide a hardcopy of the files if an electronic one is not available.

Electronic Document List

Paper Document List

No	Document Type	Description	Method	Date

Fees and Payment

Fees and Payment

Fees: AUD \$810.00

Payment Type:

Reports

Report Requested

No.	Date Requested	Report Type	Date Sent
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Report Received

No.	Date Received	Report Type
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Type Of Change

Type Of Change

Type of Change:

Change of Person in Charge of Quality & Authorised for Release.Addition of manufacturing to include, production powders & granules, uncoated, coated & chewable tablets, packaging of various products, Release for Supply.

OFFICIAL

 Australian Government Department of Health Therapeutic Goods Administration		Office of Manufacturing Quality	
MQB Form			
FORM 3.1.a	Application Receipt & Review Processing Record – Licence Applications		
Comes under	SOP 3.1 Receipt and Review of Manufacturer Licence and Certification Applications		
Process Owner	Director, Licensing & Certification	Authorised by	Quality Management
Date issued	12 September 2017	Version #	1.0

This form includes:

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Record Details	FORM 3.1.a - Application Receipt & Review Processing Record Form - Licence Applications - Variation - GMP Pharmaceuticals Pty Limited - MI-2021-LI-10110-1.DOCX Application Receipt & Review Processing Record – Licence Applications		
Last Editor	§22	Edit Date	8/01/2026 10:47 AM
Print Date	8/01/2026 10:47 AM		Page 1 of 7

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Section 1 - Application Receipt

1.1 Licence Applications – General Information			
Tracking No	MI-2021-LI-10110-1	Licence (Original Tracking No in application)	MI-2019-LI-01002-1
Manufacturer	GMP Pharmaceuticals Pty Limited		
Site Address	60 Huntingwood Drive HUNTINGWOOD NSW 2148		
Application Type	<input type="checkbox"/> New - Proceed using Section 1.2.1. <input checked="" type="checkbox"/> Variation - Proceed using Section 1.2.2 <input type="checkbox"/> Re-inspection - Proceed using Section 1.2.3		
Records Management	TRIM: Create Containers <input type="checkbox"/> Yes <input checked="" type="checkbox"/> N/A (Variations) MIS: Assign 'Assignment' task. Add 'Management Comment'. <input checked="" type="checkbox"/> Yes		

1.2 Licence Applications – Receipting	
1.2.1 For New Licence Applications	
Records Management	Record file numbers (PH, Licence/Certificate, Application Review & Inspection) to application in MIS. Save copy & supporting documents in TRIM: <input type="checkbox"/> Yes
Supporting Documents	SMF, Nominee CV's & Manu Statement supplied and saved to TRIM <input type="checkbox"/> Yes OR <u>ARCBS application:</u> Evidence provided? <input type="checkbox"/> Yes
Statutory Declaration	Statutory Test Certificate processed & saved to TRIM: <input type="checkbox"/> Yes <input type="checkbox"/> N/A (e.g. ARCBS)
Ready for Inspection Date	
MIS WM Process	Complete Assignment Task and assign Application Review task: <input type="checkbox"/> Yes

Record Details	FORM 3.1.a - Application Receipt & Review Processing Record Form - Licence Applications - Variation - GMP		
OFFICIAL	Pharmaceuticals Pty Limited - MI-2021-LI-10110-1.DOCX		
Last Editor	S22	Edit Date	8/01/2026 10:47 AM
Print Date	8/01/2026 10:47 AM		Page 2 of 7
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1.2.2 For Licence Variation Applications

Variation Type	<input type="checkbox"/> Administrative Manufacturer Details Change <input checked="" type="checkbox"/> Authorisation / Condition Change <input type="checkbox"/> Nominee Change <input type="checkbox"/> Other – Specify:
Supporting Documents and Records Management	TRIM Container ('Licence/Certification'): E19-518787 Create a subfolder for the application; Save the application copy, supporting documents and checklist in TRIM: E21-387698 <input checked="" type="checkbox"/> Yes
Other Applications	Are there other applications for the site: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> N/A If yes, Tracking Number: Record details of variation (If there are multiple variation applications, confirm the variation in combination with other applications).
MIS WM Process	Complete Assignment Task and assign Application Review task: <input checked="" type="checkbox"/> Yes
Notification	Send email to Inspector <input checked="" type="checkbox"/> Yes

1.2.3 For Licence Re-inspection Applications

Records Management	Record file numbers (PH, Licence/Certificate, Application Review & Inspection) to application in MIS. Save copy & supporting documents in TRIM: <input type="checkbox"/> Yes
Other Applications	Are there other applications for the site: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, Tracking Number:
MIS WM Process	Complete Assignment Task and assign Application Review task: <input type="checkbox"/> Yes

1.3 Complete Receipting

Initials: HD	Date: 18/10/2021
E-sign Checklist in TRIM: <input checked="" type="checkbox"/> Yes	

Record Details OFFICIAL	FORM 3.1.a - Application Receipt & Review Processing Record Form - Licence~ications - Variation - GMP Pharmaceuticals Pty Limited - MI-2021-LI-10110-1.DOCX		
Last Editor	S22	Edit Date	8/01/2026 10:47 AM
Print Date	8/01/2026 10:47 AM		Page 3 of 7
Once printed or copied from the Master, this is no longer a controlled document; check validity before use			

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Section 2 – Application Review

2.1 Application Review - Licence Applications	
2.1.1 Application Review – Licence Applications (<u>New</u>)	
Review all other applications for the site	<u>Review Outcome:</u>
Review application and supporting evidences	<u>Review Outcome:</u>
Is Inspection required?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <u>Audit type:</u> <u>Number of Auditors:</u> <u>Duration:</u> <u>Audit Qualification:</u> <u>Due Date:</u>
Generate Audit in MIS	<u>Audit No:</u>
Notify OMQ Scheduling for Initial and high priority Inspections	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
Once Review is completed, re-assign the Application Review task to 'ARIST - Reviewed'	<input type="checkbox"/> Complete

OFFICIAL

2.1.2 Application Review –Licence Applications (<u>Re-inspection</u>)	
Review all other applications for the site	<u>Review Outcome:</u>
Review Audit details	<u>Review Outcome:</u>
Is any change to re-inspection required?	<input type="checkbox"/> Yes <input type="checkbox"/> No <u>If yes, details:</u>
Notify OMQ Scheduling if high priority Inspections (e.g. lifting suspension inspection, etc)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Once Review is completed, re-assign the Application Review task to 'ARIST - Reviewed'	<input type="checkbox"/> Complete

2.2 Complete Review	
Initials:	Date: Click here to enter a date.
E-sign in TRIM: <input type="checkbox"/> Yes	

Section 3 – Peer Review

Peer review is only intended to be used for training purposes, or for periodic peer review.

The Peer Reviewer is to complete this section after reviewing sections 1 and 2 and any relevant evidence in the TRIM folder. Comments should be included in the right hand column, as applicable and appropriate.

3.1 Peer Review		
Peer review Required? <i>(If Yes select the reason for peer review)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	Training <input type="checkbox"/> Periodic Peer Review <input type="checkbox"/>
Correctly followed the review process according to SOP 3.1 and WI 3.1.1? <i>If NO, provide comment</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Conclusions of the review are appropriate? (Refer to Section 2) <i>If NO, provide comment:</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	

3.2 Complete Peer Review	
Name:	Date: Click here to enter a date.
e-sign in TRIM: <input type="checkbox"/> Yes	

OFFICIAL

Version history

Version	Description of change	Author/s	Effective date
1.0	New document	s22	12 Sep 2017

Document Change Proposal

Proposed changes to this MQB QMS Document must be initiated through the following document change proposal form: [D17-769023](#)

Record Details OFFICIAL	FORM 3.1.a - Application Receipt & Review Processing Record Form - Licence variations - Variation - GMP Pharmaceuticals Pty Limited - MI-2021-LI-10110-1.DOCX		
Last Editor	s22	Edit Date	8/01/2026 10:47 AM
Print Date	8/01/2026 10:47 AM		Page 7 of 7
Once printed or copied from the Master, this is no longer a controlled document; check validity before use			

From: s22
To: GMP
Cc: s22
Subject: RE: GMP Licence variation for GMP Pharmaceuticals Pty Limited - MI-2021-LI-10110-1 [SEC=OFFICIAL]
Date: Thursday, 11 November 2021 12:52:00 PM
Attachments: [image003.png](#)
[image004.png](#)

Hello s22

Thanks for creating the special inspection. I suspect it will stay with me as the last inspector and I have contact with the manufacturer if there are any delays.

s22 – this is a new inspection (1.5 days) that is currently scheduled for Q1 2022. Can you add this to my inspection load?

Regards

s22
GMP Inspector
Inspections Section
Manufacturing Quality Branch

s22
@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia

From: GMP <GMP@health.gov.au>
Sent: Thursday, 11 November 2021 11:41 AM
To: s22 @health.gov.au
Subject: RE: GMP Licence variation for GMP Pharmaceuticals Pty Limited - MI-2021-LI-10110-1 [SEC=OFFICIAL]

Dear s22

The Special audit for a variation MI-2021-LI-10110-1 has been created with information you provided. The inspection Trim file PH21/4608 has also been created for a variation. All the supporting document from a variation container [E21-387698](#) has been related to Application Review container [E21-407633](#).

Please note that a variation MI-2021-LI-10110-1 is currently assigned to you in MIS and may not appear on Scheduling Parcel.

Please don't hesitate to contact me if you have any queries.

Kind Regards,

s22

Departmental Officer

Licensing and Compliance Strategy Section
Manufacturing Quality Branch

Phone: 1800 020 653
Fax: (02) 6203 1451
Email: GMP@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au



GMP approach to overseas manufacturers of medicines and biologicals during the COVID-19 pandemic

Important [announcement](#) on the introduction of alternative evidence requirements for GMP Clearance as well as an overseas remote inspection program



TGA expectations for remote inspections during the COVID-19 pandemic

We have published some useful guidance on the [expectations](#) of manufacturers hosting remote overseas inspections.



TGA adoption of version PE009-14 of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products for medicines and APIs

PE009-14 took effect as the manufacturing principle in Australia on 1 July 2020. There will be a transitional period and expectations for compliance are outlined in the [transition plan](#). Compliance with all elements of the PIC/S GMP guide is mandatory from 1 July 2021.

Important: The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

Please note that this email, and any attachments, may contain confidential or legally privileged information. Please consult with the sender before disclosing any part of this email, or any attachments, to any third party. If you receive this email in error, please notify the sender immediately and delete all copies together with any attachments.

From: GMP

Sent: Wednesday, 10 November 2021 3:35 PM

To: [s22](#) <s22@health.gov.au>

Subject: RE: GMP Licence variation for GMP Pharmaceuticals Pty Limited - MI-2021-LI-10110-1
[SEC=OFFICIAL]

Good afternoon [s22](#)

I will generate a special inspection with information that you have provided. Would you like me to re-

assign a variation so it'll appear in a parcel for the Inspector Team Leaders information?

I'll leave a variation with you if you intend to inspect the manufacturer based on a variation MI-2021-LI-10110-1.

I'll request a revised Site Master File from s22 of GMP Pharmaceuticals .

Thanks s22

Kind Regards,

s22

Departmental Officer
Licensing and Compliance Strategy Section
Manufacturing Quality Branch

Phone: 1800 020 653
Fax: (02) 6203 1451
Email: GMP@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
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www.tga.gov.au



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this email in error, please notify the sender immediately and delete all copies together with any attachments.

From: s22 [redacted] <[redacted]@health.gov.au>
Sent: Wednesday, 10 November 2021 11:18 AM
To: GMP <GMP@health.gov.au>
Subject: RE: GMP Licence variation for GMP Pharmaceuticals Pty Limited - MI-2021-LI-10110-1 [SEC=OFFICIAL]

Hello s22 [redacted]

This will certainly need a special inspection. Recommended as follows:

Inspection Type: Special (Variation)
Due Date: Feb 2022 but confirmation with manufacturer required prior to scheduling
Number of Auditors: 1
Duration: 1.5 days
Auditor Qualifications: Non-sterile medicine manufacture

Note – I will advise the manufacturer that application should be amended for **Solid Unit Dosage Forms - Tablets & Solid Unit Dosage Forms - Hard Capsules** as an alternate to listing individual dosage forms.

The revised SMF can be requested prior to the special inspection.

Let me know if you need any other information.

Regards

s22 [redacted]
GMP Inspector
Inspections Section
Manufacturing Quality Branch

s22 [redacted] <[redacted]@health.gov.au>


Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia

From: GMP <GMP@health.gov.au>
Sent: Monday, 18 October 2021 10:05 AM
To: s22 [redacted] <[redacted]@health.gov.au>
Subject: GMP Licence variation for GMP Pharmaceuticals Pty Limited - MI-2021-LI-10110-1 [SEC=OFFICIAL]

Good morning s22 [redacted]

Please find the attached licence variation of GMP Pharmaceuticals Pty Limited with a tracking number MI-2021-LI-10110-1 to expand the scope of product.

For a licence variation with scope of product changes, we will need a revised site master File in support of a variation. **Please advise if you require a revised SMF and I'll contact the manufacturer accordingly.**

Link	Tracking Number	Group Identifier	Manufacturer's Name	Type	TGA	Status	Primary Street Address	State	Country
	MI-2021-LI-10110-1		GMP Pharmaceuticals Pty Limited	Variation		Under Review	60 Huntingwood Drive	NSW	AU

Trim link:

Variation container: [E21-387698](#)

Form 3.1.a: [D21-3223468](#)

Form 3.2.a: [D21-3223567](#)

Should this variation require an on-site inspection, could you please populate the following table with the required audit parameters.

Inspection Type: Special (Variation)

Due Date:

Number of Auditors:

Duration:

Auditor Qualifications:

Please note: If an inspection is required for this variation, could you please not complete the review task within MIS. Instead, could you please email GMP@health.gov.au (or provide a reply email) with your recommendations the audit parameters above (how many inspectors, duration, qualifications and any other information you deem relevant) and the L&C team will raise the audit on your behalf. The review task will be reassigned from your name to ensure that it does not appear in your active WM.

Kind Regards,

s22

Departmental Officer
 Licensing and Compliance Strategy Section
 Manufacturing Quality Branch

Phone: 1800 020 653

Fax: (02) 6203 1451
Email: GMP@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au



GMP approach to overseas manufacturers of medicines and biologicals during the COVID-19 pandemic

Important [announcement](#) on the introduction of alternative evidence requirements for GMP Clearance as well as an overseas remote inspection program



TGA expectations for remote inspections during the COVID-19 pandemic

We have published some useful guidance on the [expectations](#) of manufacturers hosting remote overseas inspections.



TGA adoption of version PE009-14 of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products for medicines and APIs

PE009-14 took effect as the manufacturing principle in Australia on 1 July 2020. There will be a transitional period and expectations for compliance are outlined in the [transition plan](#). Compliance with all elements of the PIC/S GMP guide is mandatory from 1 July 2021.

Important: The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

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From: [GMP](#)
To: s22
Bcc:
Subject: RE: Licence variation for GMP Pharmaceuticals Pty Limited - MI-2021-LI-10110-1 [SEC=OFFICIAL]
Date: Friday, 12 November 2021 9:12:32 AM
Attachments: [image003.png](#)
[image004.png](#)

Dear Mr s22

Thank you for getting back to me.

The SMF will be required before the inspection is conducted by the TGA.

Please don't hesitate to contact me if you have any queries.

Kind Regards,

s22

Departmental Officer
Licensing and Compliance Strategy Section
Manufacturing Quality Branch

Phone: 1800 020 653
Fax: (02) 6203 1451
Email: GMP@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
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From: s22 [REDACTED]@gmp.com.au>
Sent: Friday, 12 November 2021 8:44 AM
To: GMP <GMP@health.gov.au>
Subject: RE: Licence variation for GMP Pharmaceuticals Pty Limited - MI-2021-LI-10110-1 [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hello s22 [REDACTED]

Thank you for your e-mail.

The Site Master File is being amended to include the new products.
We expect that this will be complete shortly & I will forward you a copy as soon as it is completed.

Kindest of regards,

s22 [REDACTED]

s22 [REDACTED]

s22 [REDACTED]

| www.gmp.com.au

14 Amax Avenue,
GIRRAWEEEN
New South Wales 2145
Australia

60 Huntingwood Drive,
HUNTINGWOOD
New South Wales 2148
Australia



GLOBAL HEADQUARTERS:

60 Huntingwood Drive,
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New South Wales 2148

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FIND OUT MORE

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From: GMP <GMP@health.gov.au>
Sent: Wednesday, 10 November 2021 3:58 PM
To: s22 [REDACTED] <s22@gmp.com.au>
Subject: Licence variation for GMP Pharmaceuticals Pty Limited - MI-2021-LI-10110-1 [SEC=OFFICIAL]

Dear s22 [REDACTED]

Thank you for submitting a licence variation for GMP Pharmaceuticals Pty Limited with a tracking number MI-2021-LI-10110-1 to expand the scope of product.

In support of a variation MI-2021-LI-10110-1, please provide the Site Master File as stated on page 9 of the 'Requesting variations to your manufacturing licence A step-by-step guide' at the following <https://www.tga.gov.au/sites/default/files/requesting-variations-your-manufacturing-licence.pdf>

Please don't hesitate to contact me if you have any queries.

Kind Regards,

s22 [REDACTED]

Departmental Officer
Licensing and Compliance Strategy Section
Manufacturing Quality Branch

Phone: 1800 020 653
Fax: (02) 6203 1451
Email: GMP@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
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Phone +61 2 9631 9999 Fax +61 2 9631 9888
A.C.N. 063 353 006 A.B.N. 80063353006

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SITE MASTER FILE

HUNTINGWOOD

Document No: SMF001

Issue Date: 13th April 2022

Review Date: April 2025

**60 HUNTINGWOOD DRIVE
HUNTINGWOOD
NEW SOUTH WALES 2148**

**VERSION 05
April 2022**

**SITE MASTER FILE
60 HUNTINGWOOD DRIVE**

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PREPARED BY:	CHECKED BY:	AUTHORISED BY:
Name: s22	Name: s22	Name: s22
Signature: s22	Signature: s22	Signature: s22
Position: s22	Position: s22	Position: s22
Date: 13/04/2022	Date: 13/04/2022	Date: 13/04/2022

INTRODUCTION

The Site Master file is related to the GMP Pharmaceuticals production facility at 60 Huntingwood Drive, Huntingwood, New South Wales 2148.

At the time of this document's preparation the facility was still undergoing renovation.

The site has been issued the Therapeutic Goods Administration (TGA) license (No.: MI-2019-LI-01002-1) for:

- The manufacturing of the solid dose form: Tablet Orally Disintegrating.
- The manufacturing of the solid dose form: Tablet Chewable
- The manufacturing of the solid dose form: Tablet, Uncoated
- The manufacturing of the Dosage Form: Powder.
- The storage of all dosage form.
- Physical Testing for all dosage form.
- Chemical Testing for all dosage form.
- Microbiological Testing for all dosage form.

The site has been issued Food manufacture Licence (No.: 25372) by New South Wales Department of Primary Industry and Biosecurity (NSW Food Authority).

The site has been registered by Commonwealth Department of Agriculture for Registration as Reg. Est. 1405. The site has been granted as an Export (Dairy) for dried milk and dried milk products, goat milk powder products producing, loading and storing Establishment.

The site has been issued Organic Certification (No.: 2638P) by National Association for Sustainable Agriculture (NASAA).

An application has been made for Therapeutic Goods Administration (TGA) licensing for:

- Capsule, Enteric
- Capsule, Hard
- Capsule, Modified release
- Tablet, Effervescent
- Tablet, Film coated
- Tablet, Enteric coated
- Tablet, Modified release
- Granules.

An application has been made to the GACC.



SITE MASTER FILE 60 HUNTINGWOOD DRIVE

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1. GENERAL INFORMATION

1.1. The Company

Company Name

GMP Pharmaceuticals Pty. Limited

Company Name (Former)

Nature's Nutrition. The company was initially established in 1994 under the name Nature's Nutrition.

The name was changed to GMP Pharmaceuticals in 1999 to reflect a change in the company practices. Previously it was mainly a Sponsor of complimentary medicines with no manufacturing under its control but in 1999 the decision was made to become a manufacturer as well as a packer of therapeutic products and the name GMP Pharmaceuticals was selected.

1.2. Location of the Huntingwood Site

60 Huntingwood Drive, Huntingwood, New South Wales 2148.

1.3. Site Annexes

15 Long Street, Smithfield, New South Wales 2164 (storage only)

1.4. Other Company Locations but Independent of the Huntingwood Site

- 7 to 9 Amax Avenue, Girraween, New South Wales 2145.
- 14 Amax Avenue, Girraween, New South Wales 2145.
- 36 Amax Avenue, Girraween, New South Wales 2145.

1.5. Activities (Current) at the Huntingwood Site

Head Office and Administration.
Research and Development.

Food Processing (NSW Primary Industry).
Manufacturing of Tablet, Powders (TGA licensing).
Chemical and Physical Testing.
Microbiological Testing.

Storage (all dosage forms, TGA licensing)
Manufacturing, Loading and Storage for dried milk products (Dairy for Export) Department of Agriculture
Registered Establishment No. 1405.

1.6. Activities (proposed and future) at the Huntingwood Site

Processing of Dairy Product, dry powder (Department of Agriculture License).

Manufacturing of
Capsule, Enteric
Capsule, Hard
Capsule, Modified release
Tablet, Effervescent
Tablet, Film coated
Tablet, Enteric coated
Tablet, Modified release
Granules.
(Therapeutic Goods Administration License, applied for).

1.7. Activities at other Independent GMP Pharmaceuticals Sites

Therapeutic (TGA Licensed):
Packaging and labelling, all solid, semi-solid and liquid dosage forms.

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Manufacture of soft gel capsules.
Manufacture of hard-shell capsules.
Manufacture of tablets, uncoated and coated.
Manufacture of powders.
Manufacture of liquids.
Manufacture of lotions, semi-solids and creams.
Release for Further Processing.
Release for Supply.
Physical testing.

Therapeutic (APVMA, Australian Pesticide, Veterinary Medicine Authority Licensed):
Same as Therapeutic (TGA).

Dairy (domestic and export):
Mixing of dry dairy powders, including dairy by definition.
Re-packaging dry dairy (bovine) powders including dairy by definition.
Manufacture of dairy tablets.
Manufacture of dairy hard shell capsules.

Food:
Products similar to therapeutic but not for therapeutic supply.
Manufacture of nutritional items.
Manufacture of health foods.
Manufacture of nutritional supplements.
Packaging and labelling of food products.

Cosmetics:
Manufacture of liquids, lotions, semi-solids and creams.
Packaging and labelling of cosmetics.

Organic:
Manufacture of Organic Certified products.
Packaging and labelling of organic products.

Miscellaneous:
Importation and distribution of health foods, nutritional supplements as well as cosmetics.
Importation and distribution of raw materials and packaging materials.
Design, production and importation of labels and other printed materials.

1.8. Licenses and Registrations at 60 Huntingwood Drive

Department of Agriculture Reg. Establishment (Reg. Est 1405) Manufacturing, Loading and Storage of dry Dairy Powders.

Product Manufacture Therapeutic Goods Administration (TGA No.: MI-2019-LI-01002-1) for Tablet, orally disintegrating.

Product Manufacture Therapeutic Goods Administration (TGA No.: MI-2019-LI-01002-1) for Tablet, Chewable

Product Manufacture Therapeutic Goods Administration (TGA No.: MI-2019-LI-01002-1) for Tablet, uncoated

Product Manufacture Therapeutic Goods Administration (TGA No.: MI-2019-LI-01002-1) for Powder

Chemical and physical testing Therapeutic Goods Administration (TGA No.: MI-2019-LI-01002-1) for all dosage forms.

Microbiological testing Therapeutic Goods Administration (TGA No.: MI-2019-LI-01002-1) for all dosage forms.

NSW Department of Primary Industry and Bio-Security (Food) # **25372**.

National Association for Sustainable Agriculture (NASAA) Registration 2638P

1.9. Licenses and Registrations at other GMP Pharmaceuticals sites:

Therapeutic Goods Administration (TGA) 7 to 9 Amax: MI-21042005-LI-000516-1

GMP Pharmaceuticals Pty. Ltd.
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Document 8

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Therapeutic Goods Administration (TGA) 14 Amax: MI-2016-LI-12063-1

Department of Agriculture (Export Dairy) 7 to 9 Amax: Reg. Est.: 1202
Department of Agriculture (Export Dairy) 14 Amax: Reg. Est.: 2255

NSW Dept. Of Primary Industry and Bio-security: 7 to 9 Amax License 25372
NSW Dept. Of Primary Industry and Bio-security: 14 Amax License 25372

Australian Pesticide, Veterinarian Medicines Authority License 2205

National Association for Sustainable Agriculture (NASAA) Registration 2638P

1.10. Company Contacts

Company Name: GMP Pharmaceuticals Pty. Limited.

Site Address: 60 Huntingwood Drive, Huntingwood, New South Wales 2148.

Postal Address: Refer to site address.

Telephone Number: (currently) (02) s22

Fax Number: (currently) (02) s22

e-mail: info@gmp.com.au

e-mail s22@gmp.com.au

e-mail s22@gmp.com.au

e-mail s22@gmp.com.au

e-mail s22@gmp.com.au

24 Hour Contact Number s22

A.B.N.: 80 063 353 006

A.C.N.: 063 353 006

1.11. The Site (60 Huntingwood Drive):

The Huntingwood site is located in an industrial area 7km West of the Girraween facilities. It is located on a major secondary road (Huntingwood Drive) in the suburb of Huntingwood.

Immediately across the road is Arnott's Biscuits and a park. To the left, when facing the building, is the Eastern Creek Tavern, then two transport companies, a food manufacturer, an importer, New South Wales Police Highway Patrol base. At the rear is a building materials supplier, a cosmetics supplier. To the right is a distribution warehouse.

The building structure is about 20 to 25 years old. It consists of a concrete and steel skeleton on which walls and other materials have been affixed to create rooms and working areas. The total floor area is approximately 17,2000 sq.metres. Of this, the office areas are 3,375 sq.m., the plant room is 116 sq.m., and the production and stores areas are 13,369 sq.m. The inner areas of the building are being fully refurbished to accommodate the production activities as well as the analytical and microbiological testing areas. Also to be included will be a purpose built R and D area. This to enable trials to be conducted in an isolated area away from the production areas. The floors are essentially reinforced concrete with walls and ceiling constructed of sandwich or insulation panel.

The size of the block of land is 27,340sq.m. Apart from the basic buildings, it includes landscaped areas as well as car parks.

1.12. Employees:

The site is new to GMP Pharmaceuticals and the introduction and commissioning of new activities has commenced and is on-going. As production expands there will be an increase in production as well as support staff.

The following numbers are expected to increase significantly when full production is achieved.

The numbers are related only to production and direct support staff such as maintenance, quality departments, stores as well as technical. The numbers do not include general office, accounts, customer services, IT, sales and marketing staff.

Production:	30
Production Planning:	2
Quality Assurance & IPQC:	7
Quality Control (Analytical):	10
Microbiological Analyst:	2
Maintenance:	2
Regulatory:	1
Storage and distribution:	4
Engineering, Facility:	6
Total:	64

It is expected that from time to time there will be a need for casual staff in the production areas. These staff will be employed on an "as required" basis and will be limited to performing simple packaging work.

The frequency of use, as well as the numbers of casual staff will be minimised where possible.

1.13. External Technical Services:

These are to be determined.

1.14. Quality Management:

The Quality Policy of the Company is:

"GMP Pharmaceuticals Pty. Limited is a provider of contract manufacturing and packaging services for pharmaceutical and nutritional products and is dedicated to providing products and services to a standard, based on "The Code of Good Manufacturing Practice", the current Pharmaceutical Inspection Co-operation Scheme (PIC/s) issued in 2017 is the basis on which therapeutic systems are based. It is our hope to meet or ideally exceed the quality expectations of our many local and international customers.

It is one of our objectives to be recognised as a leader and innovator in our industry. One aspect of achieving this objective is the establishment of a Quality System. We believe that our Quality Systems are suitable to provide the necessary confidence that the quality needs of our customers, in addition to the requirements of "The Code of Good Manufacturing Practice" are satisfied in the products and services that we provide. Additionally, that the necessary controls are consistently and adequately applied to meet them. We believe that among other considerations to achieve this objective and to ensure we provide the highest possible standard of service; we should be supportive and committed to working with our customers to identify what



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their expectations as well as their stated and implied needs are. We also acknowledge that we should develop a partnership with our customers to maintain and continuously improve the quality of the products and services that we provide, thereby improving the quality of our operations and enhancing the benefits we provide.

We understand that to achieve these objectives we should, amongst other considerations promote the skills acquisition of our employees and to promote the concepts and benefits of quality throughout the organisation thereby encouraging the further commitment of our personnel to producing products of the highest standard.

As a respected corporate citizen, we affirmatively accept our obligation to achieve and maintain a high standard of environmental responsibility commensurate with our position within our industry as well as the community.

GMP Pharmaceuticals is committed to be an international best practice competitive food and pharmaceutical manufacturer meeting or exceeding its customer's needs.

A systematic approach is used to integrate the principles of continuous improvement throughout all levels and functions of the organisation, involving all management and employees and working in partnership with our customers and suppliers to achieve the stated food and pharmaceutical safety and quality objectives.

The food safety and quality system (including HACCP, export and importing country requirements) are adhered to at all times ensuring a reliable and hygienic manufacturing procedure to maintain product integrity, built on high quality ingredients to achieve the best possible product to fulfil our customers' expectations and requirements."

The food safety and quality system is continually reviewed, and upgraded as appropriate, to achieve continual improvement of product quality in response to changing customer demands, or system/process improvements. Adequate resources are provided for the implementation, control and review of the food safety and quality system.

The company is committed to producing safe, suitable products in compliance with all legislative requirements and ensuring that no procedure within the Food Safety and Quality System takes precedence over any requirement of the ANZ Food Standards Code, the Export Control Act and the subordinate legislation and regulations.

The Food Safety and Quality Manual is maintained as an integral element of the company culture, recognizing and encouraging full participation of all employees in the development and maintenance of the food safety and quality program.

The Quality Assurance (QA) function of the Huntingwood site has the responsibility of ensuring that all the relevant aspects of the Code of Good Manufacturing Practice are adhered to. QA also has the responsibility of ensuring that specifications are complied with and that a safe, efficacious and consistent product that is free from contamination is delivered to our customers.

With regard to the organisational structure, the QA supervisor Huntingwood reports directly to the Site Manager or equivalent. Currently, there are four QA personnel reporting to the QA supervisor and they are in charge of implementing the various aspects of the Quality System as well as their day to day applications. The Quality Management System will be based on the Code of Good Manufacturing Practice for therapeutic products as well as the requirements of the New South Wales Department of Primary Industries and Bio-security requirements. Additionally, the requirements of the Export (Milk and Milk Products) Control Orders 2005 will be incorporated.

Specifications have been established for raw materials that are based on the appropriate compendia or another suitable references. Sampling and test procedures have been established for all incoming raw and packaging materials and have ongoing documentation for data collection and trend analysis.

An internal review programme has been initiated where Standard Operating Procedures (SOP) are evaluated for compliance and suitability at the time of their date of review.

In regards to internal and other audit reports, these are documented with a written corrective action request prepared and brought to the attention of the appropriate manager and a written reply is required. A compliance

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record is maintained with any undertakings and times for remedial action in the reply. As the business is still relatively small, any non-compliance with the SOP as well deviations from approved housekeeping practices should be observed during inspections and audits as well as tours of the various areas.

Standards such as ISO 9000 to 9004 do not have formal recognition at the present time. However, informal credence is given to these certifications when determining what quality control procedures are required for goods received from suppliers/manufacturers.

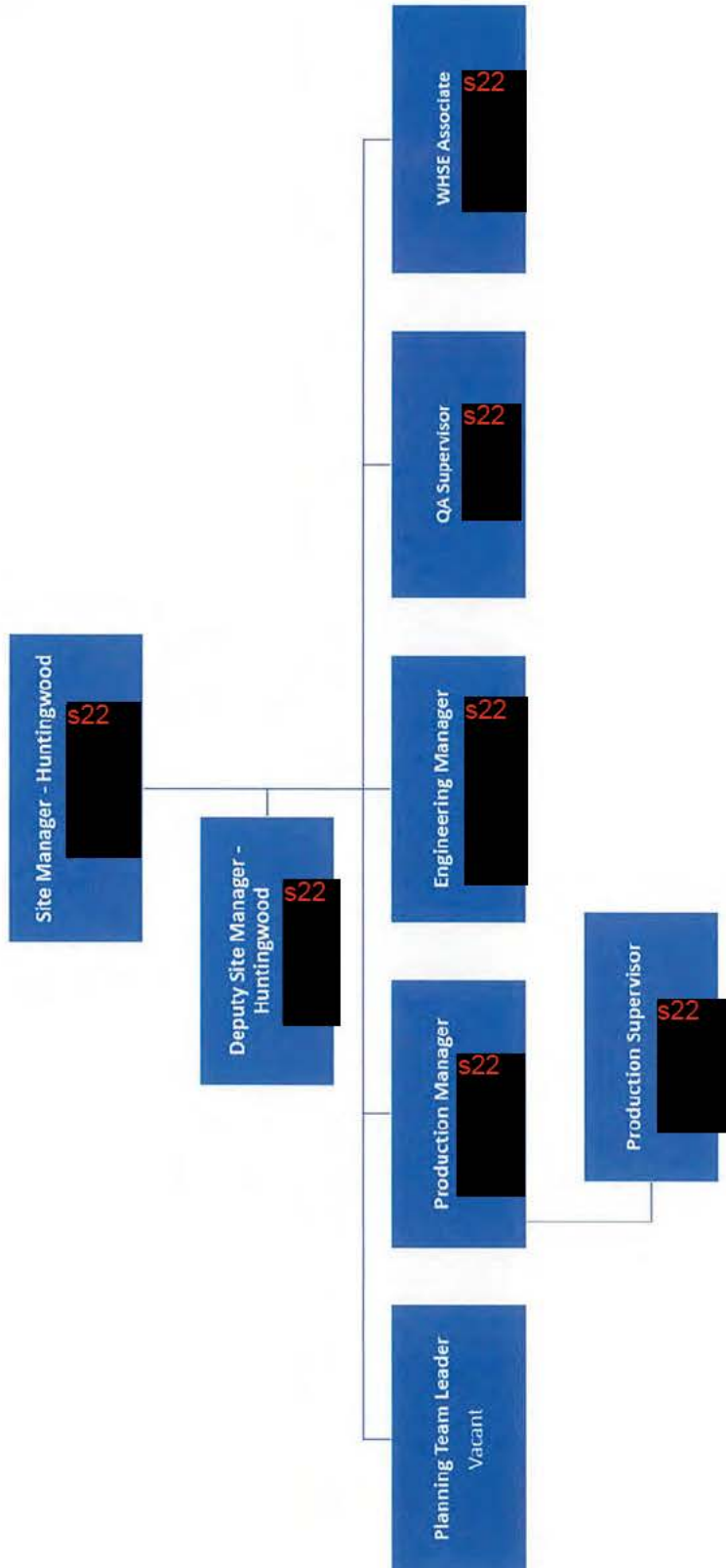
Suppliers of critical raw and packaging materials shall be assessed on what, if any, certification they have, then on their general reputation with regard to quality. Deliveries of these goods will be subjected to a level of quality control adequate to provide the level of confidence necessary for their use.

The "Release for Supply" (Therapeutic) or equivalent procedures for products manufactured on this site requires that all manufacturing and packaging documentation be evaluated including the results of the reconciliations. Only if the requirements of the evaluation process are complied with, will the product be "Released for Supply" or its equivalent.

For products contract manufactured by another manufacturer, who must have a current TGA license (Therapeutic) or HACCP (Food), or Organic Certification (Organic) or Department of Agriculture registration (specific to the requirements of our registration), the requirements are an acceptable certificate of analysis from the primary manufacturer. Also, all packaging records and reconciliations are evaluated. Only if the requirements of the evaluation process are complied with will the product be release as appropriate.

2. PERSONNEL

2.1. Organisational Chart.



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2.2. Key Personnel and Their Qualifications.

Managing Director: s22

s22

Chief Operating Officer: s22

s22

Site Manager (Huntingwood): s22

s22

Deputy Site Manager (Huntingwood): s22

s22

Quality Manager (Huntingwood Chemical & Microbiological Laboratories): s22

s22

Production Manager (Huntingwood): s22

s22

Quality Assurance Supervisor (Huntingwood): s22

s22

s22

Quality Control Lab Manager: s22

s22

2.3. Basic and In-house Training.

Currently, the training needs of the personnel may be determined by a number of means and consists of a multi-level approach.

1- Pre-deployment

After initial employment by the company but before employees begin performing duties within the production areas, they will be provided with simple training to ensure that they have a basic understanding of what is required of them. Operators will be given an outline of what is acceptable conduct within the working area. For example, all staff that perform duties directly related to the production or manufacture of therapeutic goods are required to have a basic understanding of hygiene as well as document control and data entry. While those involved with the production of dairy & food products will be additional training in sanitation.

2- Induction

Induction will be in the form of a structured program where new employees will be trained in the basic requirements related the Therapeutic Good Manufacturing Practice or Dairy and Food Manufacture as well as the necessary information related to hygiene and sanitation as related to food products.

3- GMP Training Program

This is a structured multi-module in-house training program. One of the main functions of the training program is to enable the various staff members to understand and appreciate the aims of the Code of Good Manufacturing Practice. This enables them to understand the procedures that they will be expected to follow. Included within this program will be training relevant to dairy products as well as foods. Staff are assigned duties relative to their understanding of the Code as well as their level of training.

4- SOP Training;

This will include training in Standard Operating Procedures, the various documents that are used, the specific use of equipment, general aspects of Good Manufacturing Practice and their duties.

5- Evaluation

Currently, the efficacy of the training is assessed by conducting quizzes designed for each SOP as an addendum to SOP and/or evaluating trainee's job performance. The assessment of the training is currently determined at the time of training and consists of evaluations that the trainees are required to undertake. If a trainee is determined not to be trained to an acceptable standard, they may be provided with further training to raise their standard or they may be assigned duties suitable to their demonstrated level of ability

A Training Record and Log System has been developed where logs are maintained showing the various units of training that the personnel have received.

2.4. Health Requirements of Personnel.

Prospective production staff are required to undergo a medical examination and provide documentary evidence that they are medically fit and that their health is suitable for work within the particular part of the pharmaceutical or dairy and food industry with which this business is concerned. All staff will be required to notify their respective manager if their health deviates from this requirement. Generally, the various departmental managers will be responsible for the health of the employees in their respective areas with the

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QA Manager having the additional responsibility of monitoring staff within the production area in conjunction with the Production Manager. Staff will not be permitted to work in the production area if they have any infections, lesions, wounds or injuries that have not been adequately treated and dressed. These requirements will be included in the in-house training programme. There are no critical areas that require a more detailed procedure at the present time.

2.5. Personal Hygiene and Sanitation.

There are adequate washing, changing and rest areas provided for all personnel. There are a number of areas throughout the premises that provide changing area facilities, personal lockers, showers, hands free hand washing area, hot air hand dryers, male and female toilets. Additionally, there are male and female toilets available in the office areas and which also provide, hand washing facilities and hot air hand dryers. All areas are readily accessible to all staff.

The protective clothing supplied to staff consists of a coat or gown which may have the company logo on it. Visitors will be provided with a similar coat. All persons entering the TGA areas will be required to wear approved gowns, hair coverings, shoe covers, facemasks and bear covers as well as any other appropriate protective items.

Sterile disposable gloves are also provided for use when required.

Staff are required to put on clean new gowns and other items each time they enter or re-enter a production area. There are sufficient coats to ensure a supply of clean new gowns or coats are available at all times. Coats are collected regularly and laundered before re-use.

Staff are required to maintain a high level of hygiene and sanitation while in the production areas with sanitisation stations being readily available.

The company has a jewellery and other procedures to minimise the potential for foreign objects or other personal contaminants affecting products.

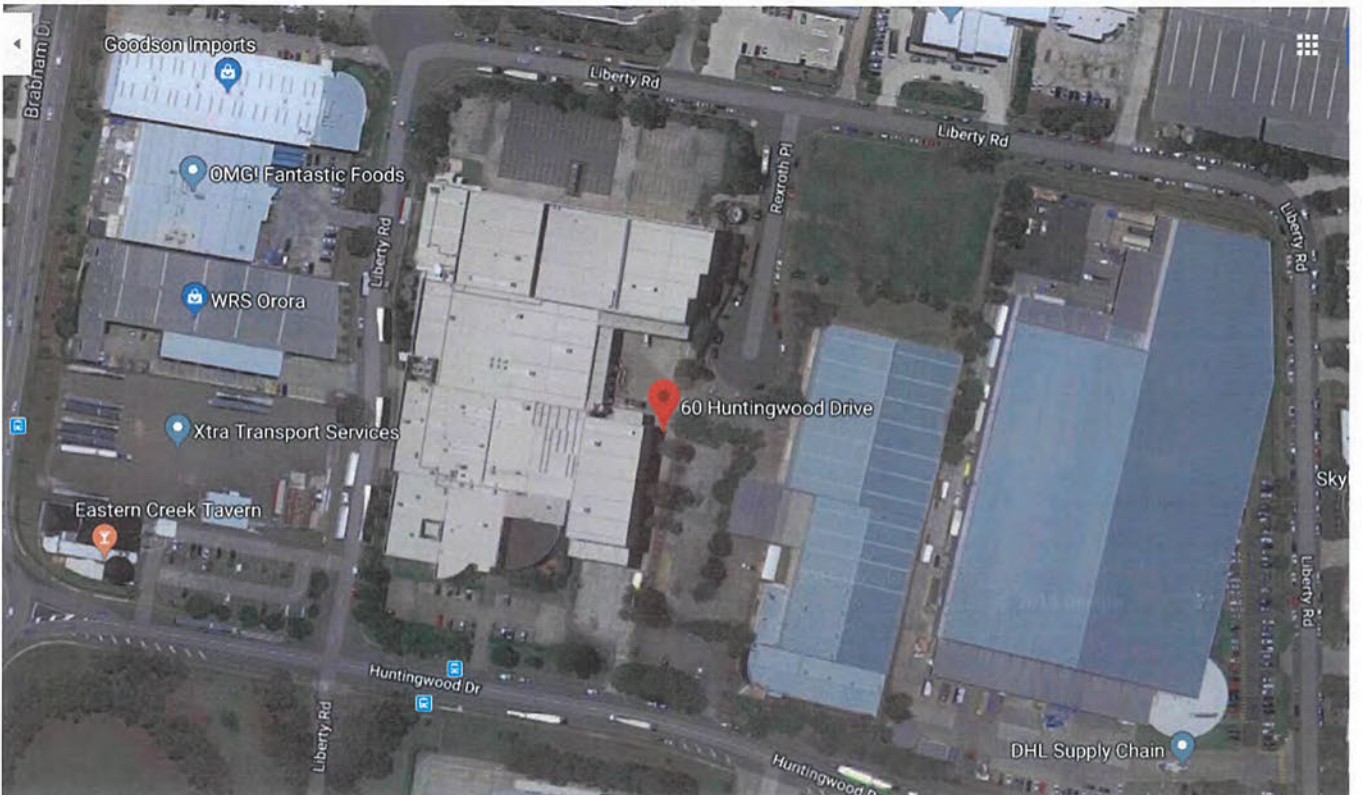
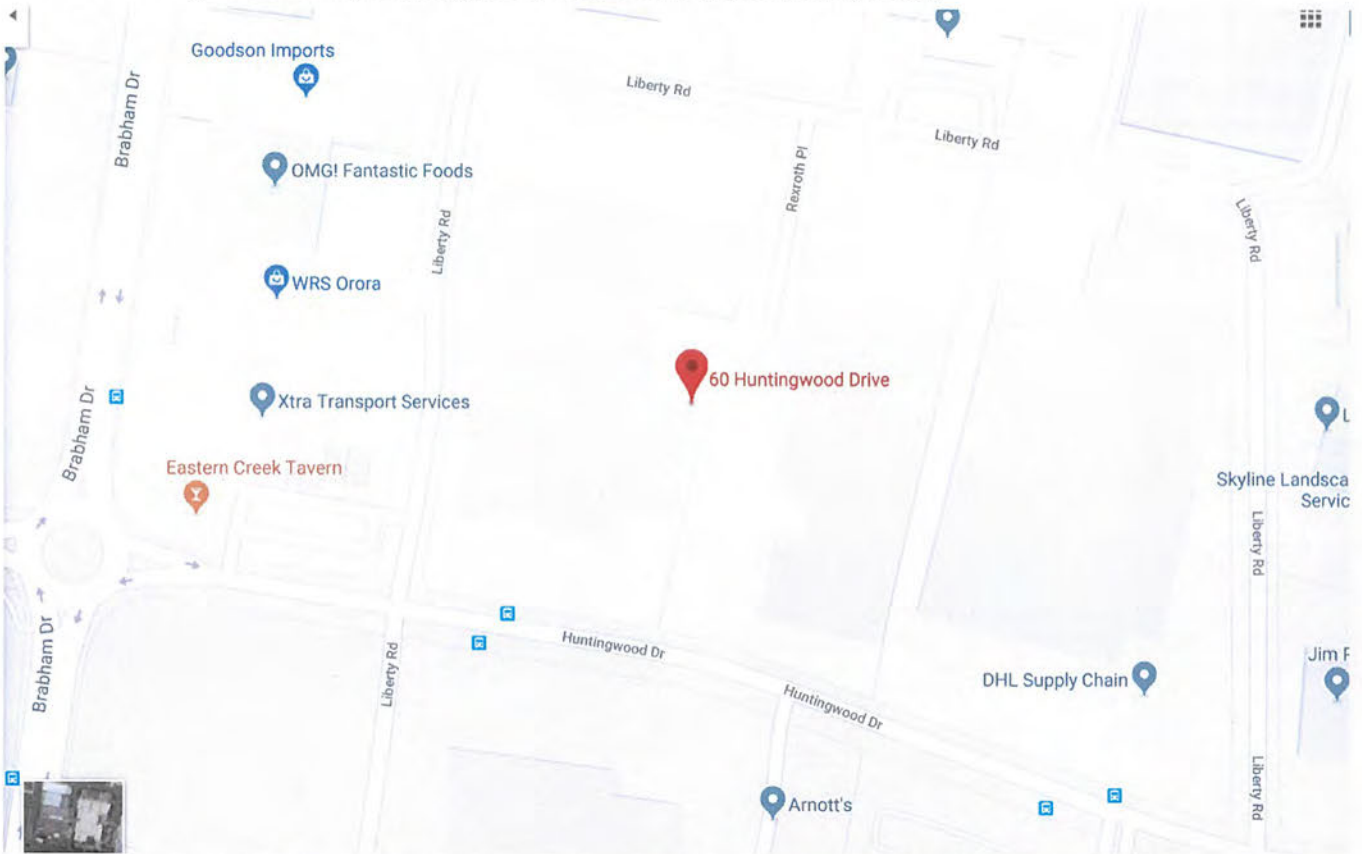
Areas are colour coded to minimise the potential for contaminants and allergens being carried from one area to another. All cleaning equipment where practical, comply with the requirements of the colour coding system.

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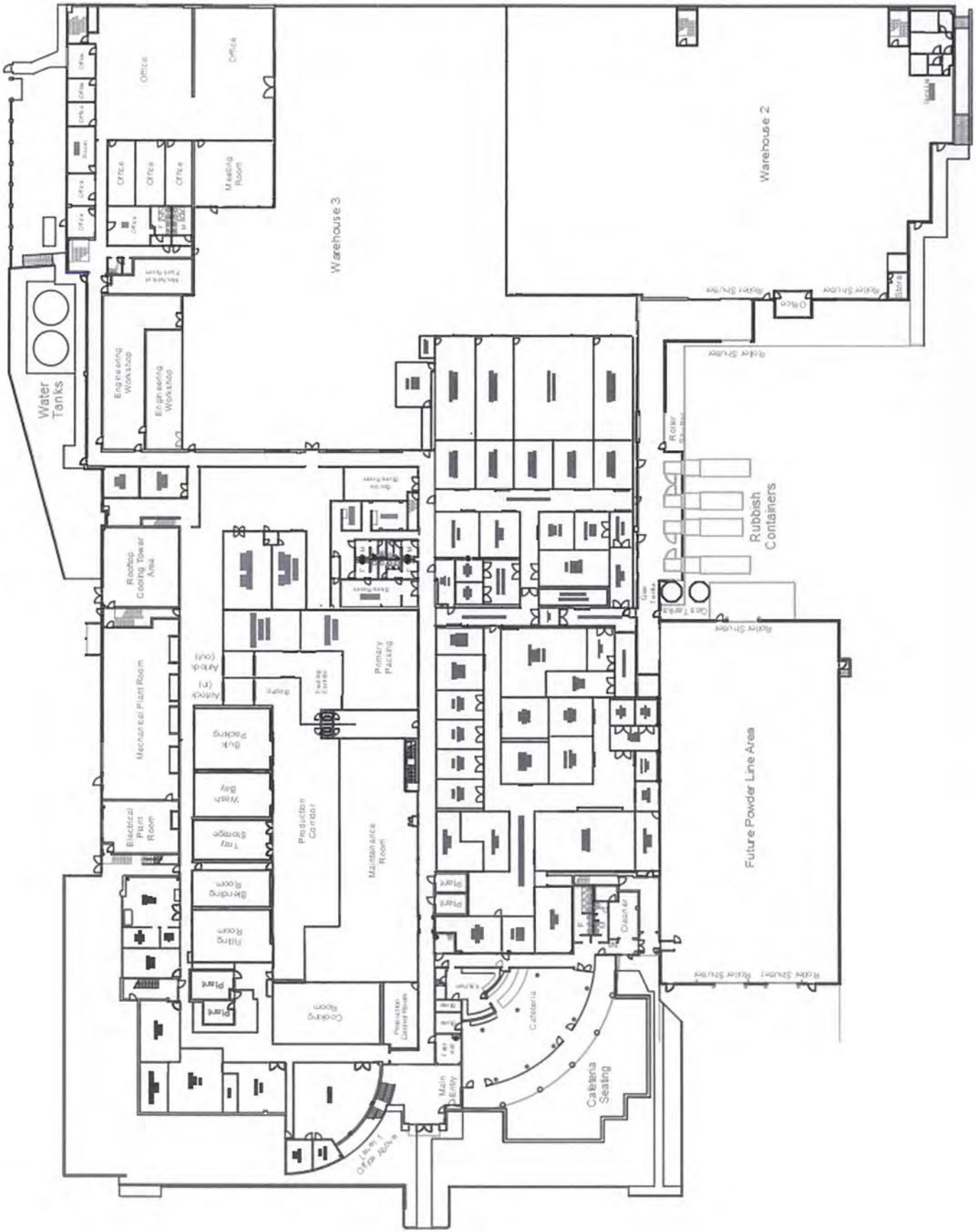
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3. PREMISES

3.1. 60 Huntingwood Drive, Huntingwood, New South Wales 2148 (Aerial)



3.2. Buildings





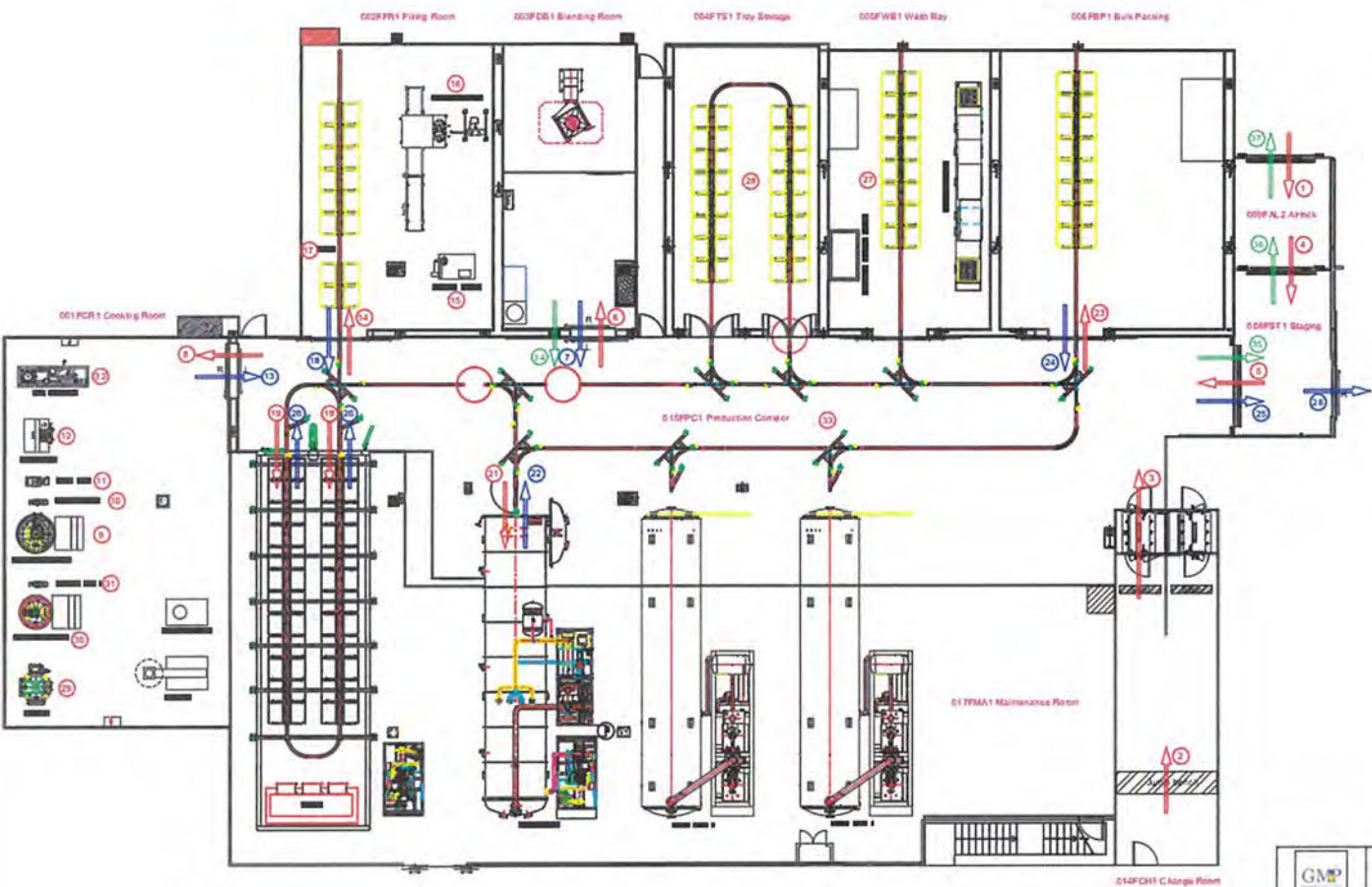
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Freeze Dry Production Flow Chart

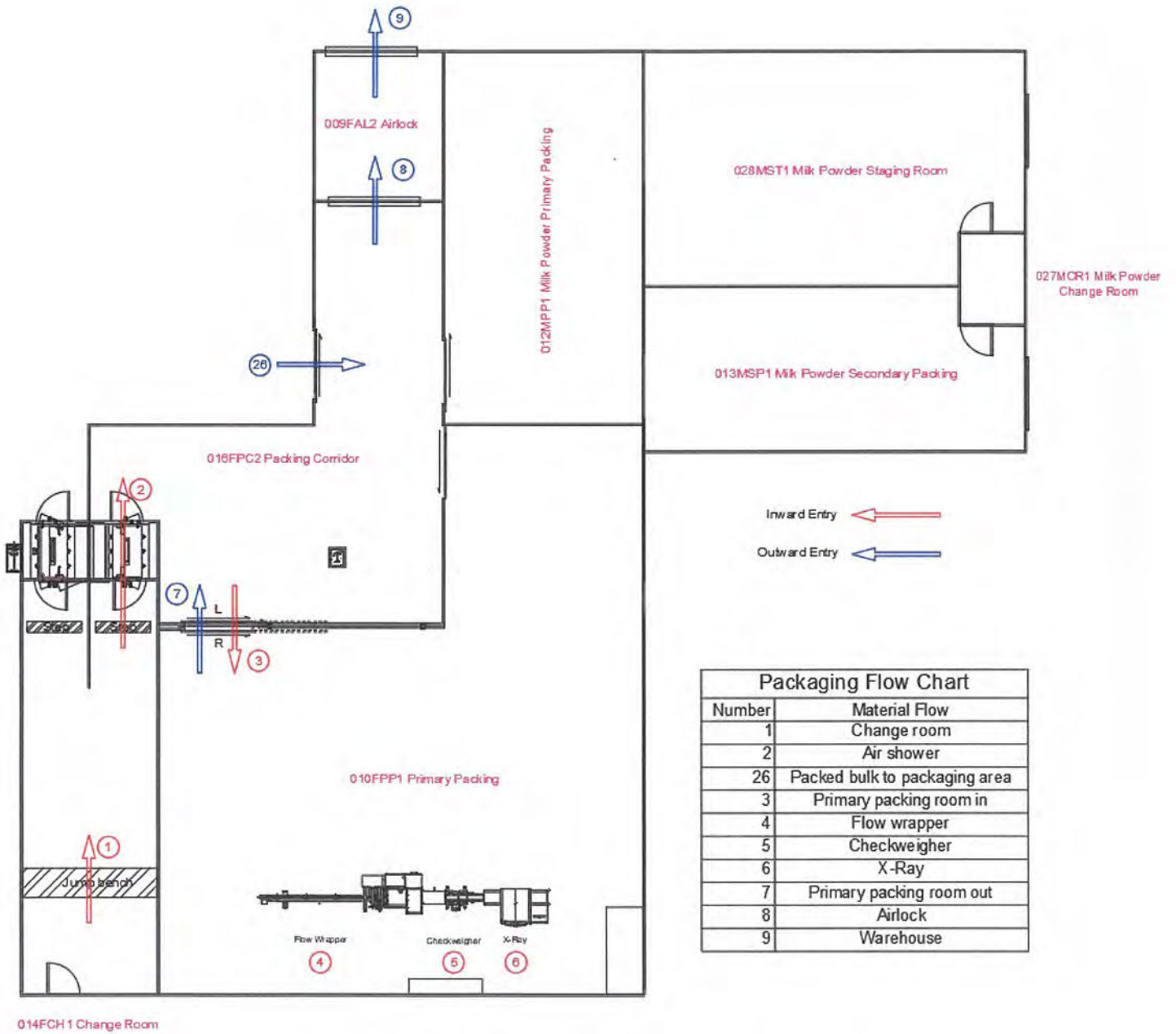
Number	Material flow
1	Airlock raw material entry
2	Change room entry
3	Air shower
4	Material transferred to staging area
5	Production corridor
6	Dispensing raw material
7	Dispensed material transferred out
8	Cooking room
9	Material cooked in 1000L tank
10	Material pump 2
11	Shear pump
12	Homogenizer
13	Cooked material transferred out
14	Filling room
15	Aeration machine
16	Depositor machine
17	Mould in trolley
18	Trolley transferred out
19	Freezer in
20	Freezer out
21	Freeze dryer in
22	Freeze dryer out
23	Bulk packing room
24	Packed bulk out
25	Packed bulk to staging area
26	Packed bulk to packaging area
27	Wash bay
28	Tray storage
29	CIP tank
30	600L cooking tank
31	Material pump 1
32	Heat exchanger
33	Monorail
34	Raw material return to corridor
35	Raw material return to staging area
36	Raw material return to airlock
37	Raw material return to warehouse



	PRODUCTION FLOW CHART	13/01/2020
YOM:GLJ	ANTHONY SALESKIN	PRODUCTION

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Freeze Dry Packaging Flow Chart

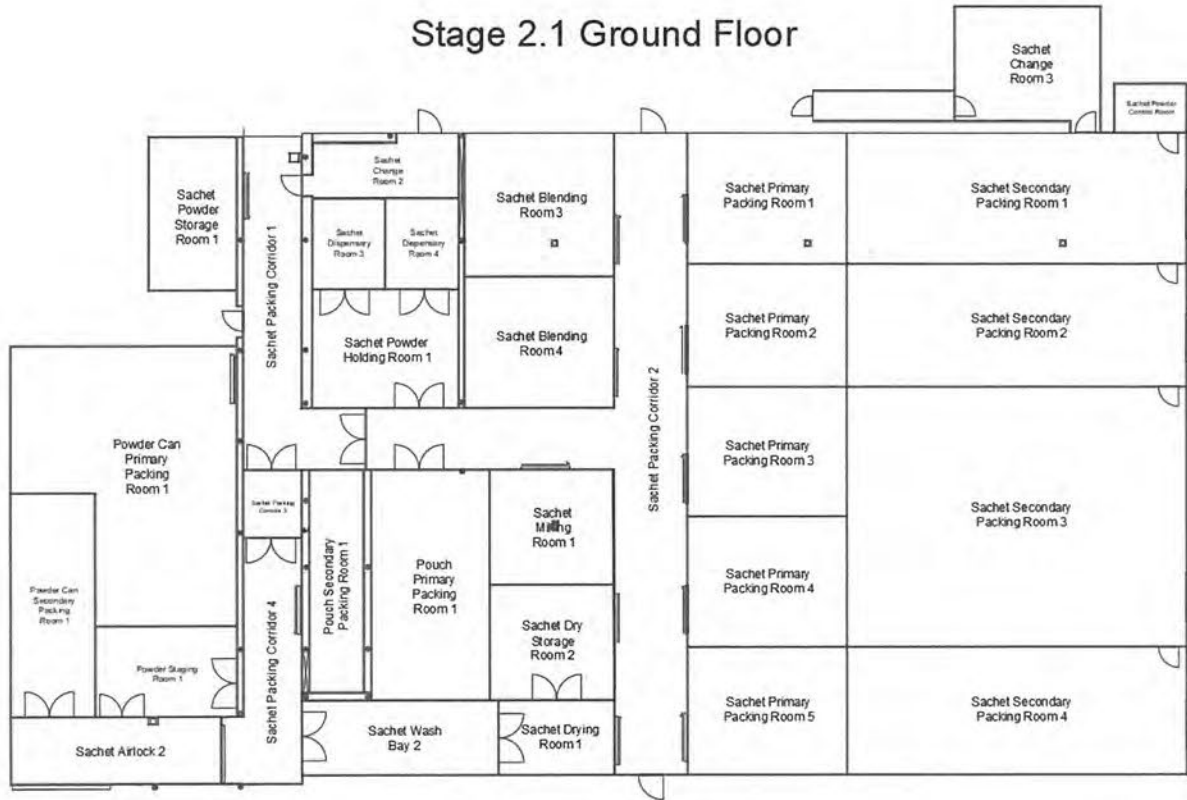


Packaging Flow Chart	
Number	Material Flow
1	Change room
2	Air shower
26	Packed bulk to packaging area
3	Primary packing room in
4	Flow wrapper
5	Checkweigher
6	X-Ray
7	Primary packing room out
8	Airlock
9	Warehouse

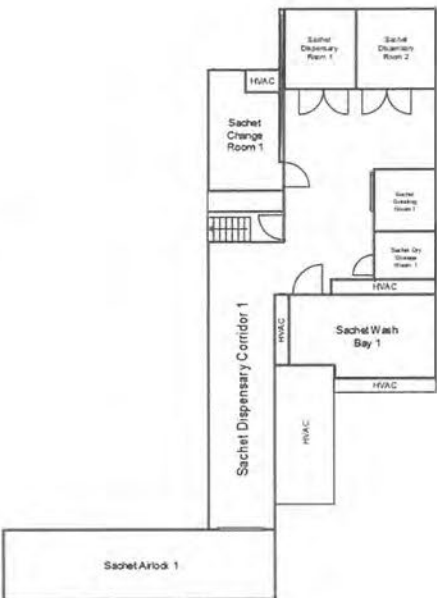


Powder and Sachet Line Flow Chart

Stage 2.1 Ground Floor



Stage 2.1 Mezzanine

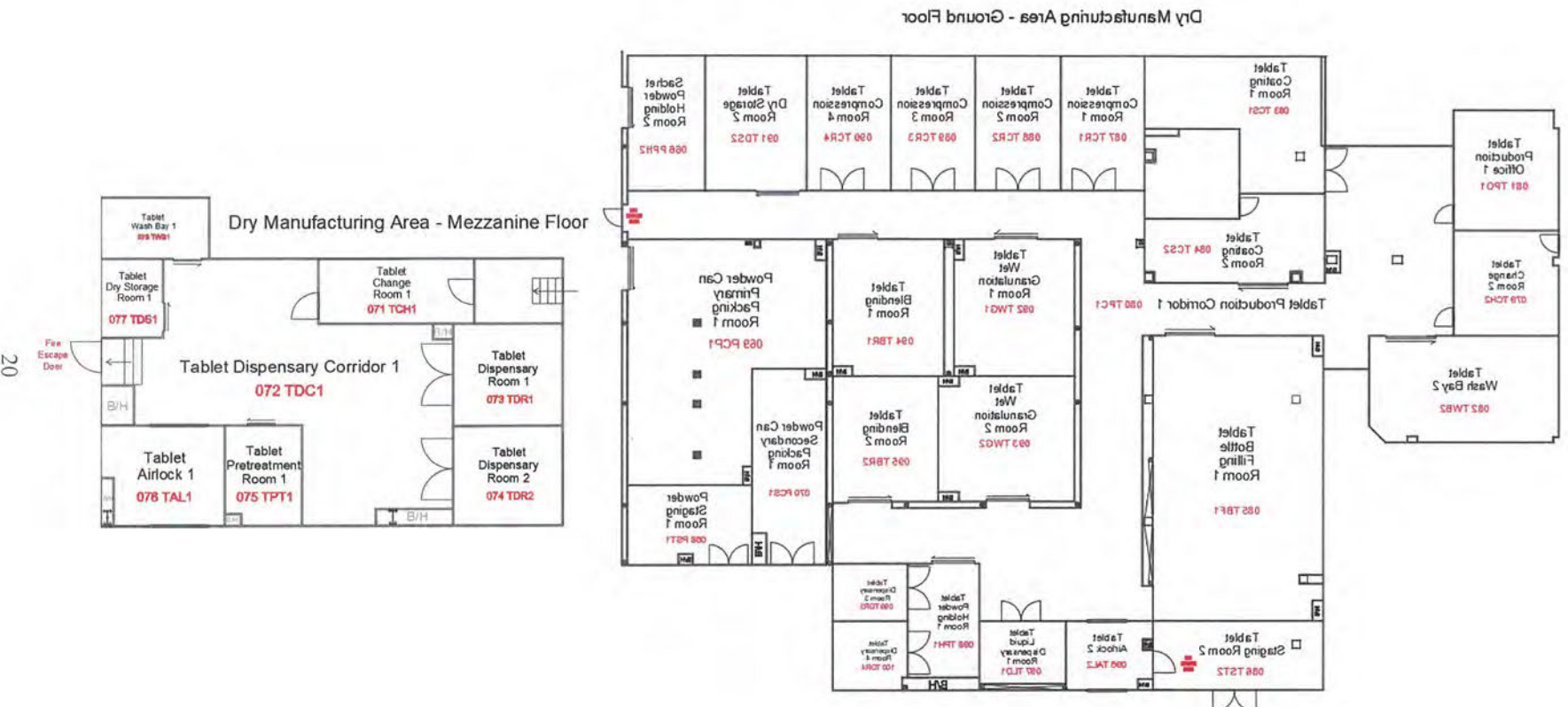




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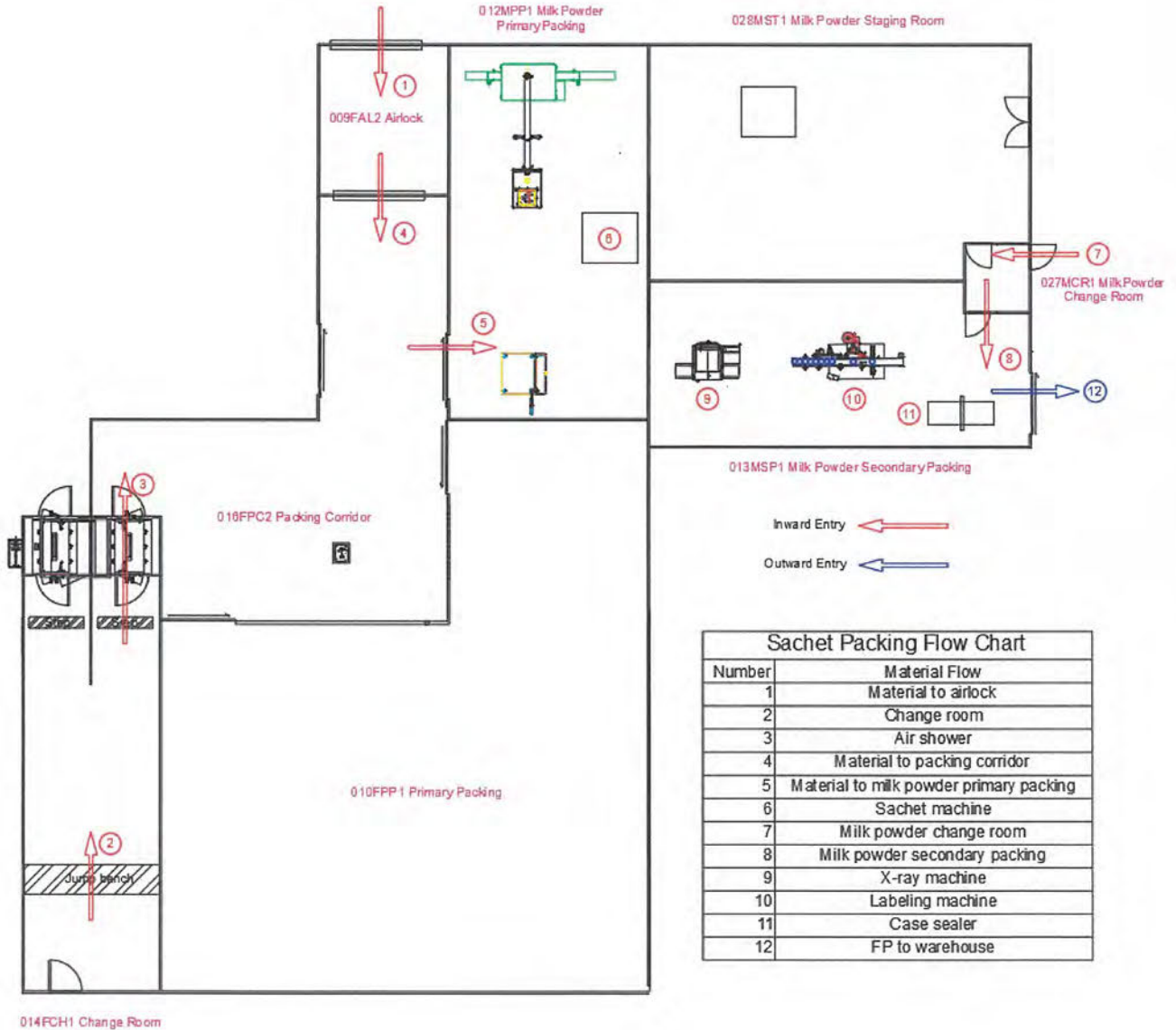
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Tablet Line Flow Chart



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Powder Packing Flow Chart



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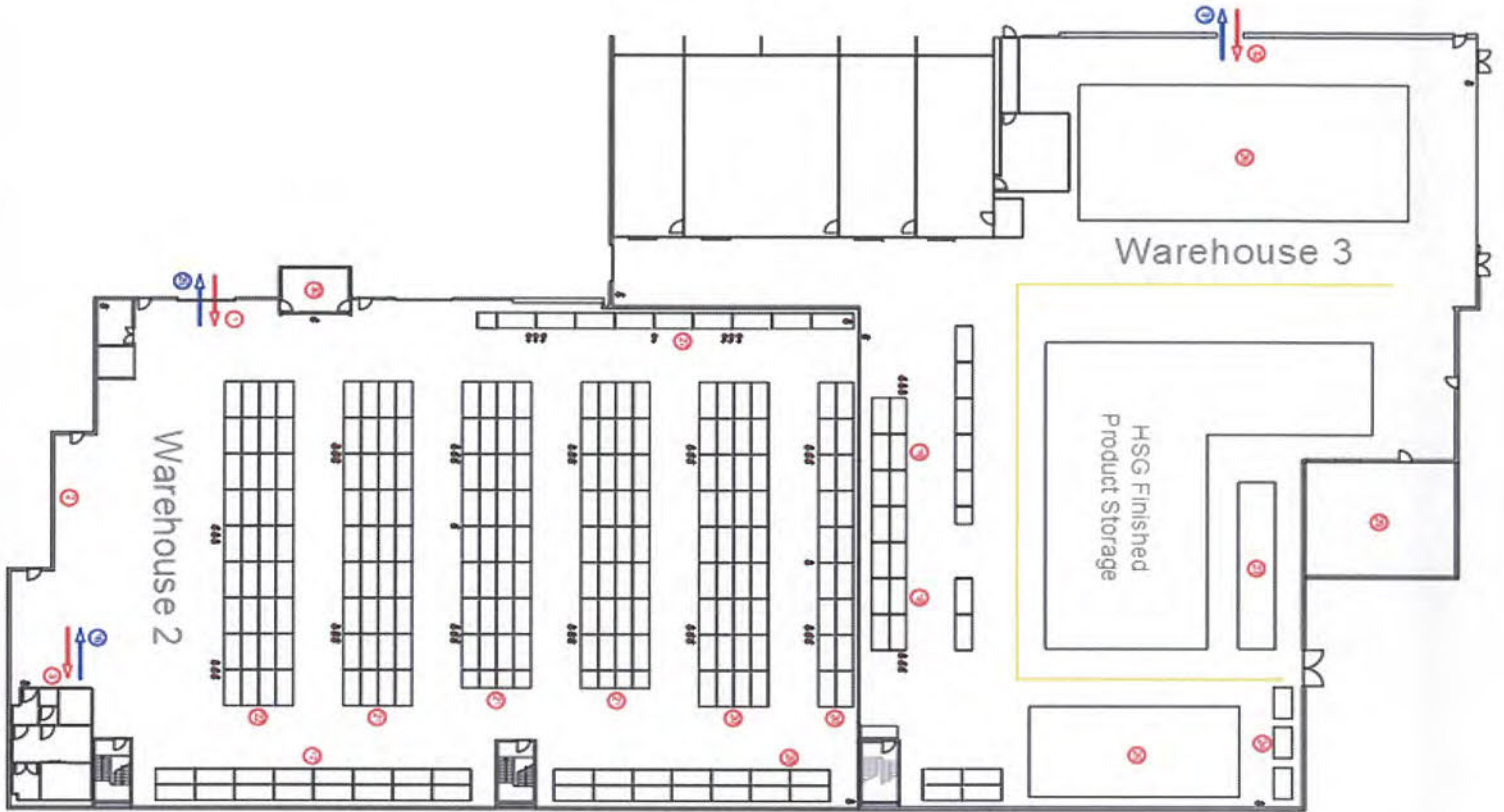
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Chemical and Micro Lab Area

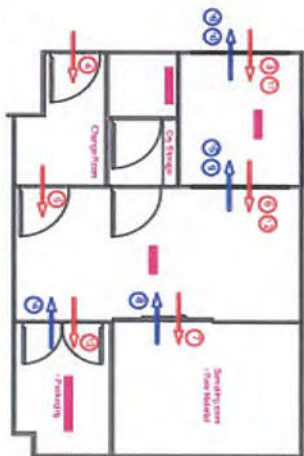


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Warehouse Flow Chart



Warehouse Flow Chart	
Number	Material Flow
1	Warehouse entry
2	Raw material staging
3	Raw material to a stock
4	Change room
5	Corridor
6	Raw material to corridor
7	Sampling room (raw material) in
8	Sampling room (raw material) out
9	Raw material to a stock
10	Raw material from a stock
11	Packaging material to a stock
12	Packaging material from a stock
13	Sampling room (packaging) in
14	Sampling room (packaging) out
15	Packaging material to a stock
16	Packaging material from a stock
17	Raw material quarantine
18	Preparation raw material
19	Non-sterilized raw material
20	Packaging material quarantine
21	Packaging material a stock
22	Customer supplied packaging material
23	Corridor
24	Freezer
25	Consumption
26	Finished product quarantine
27	Finished product review
28	Repack and hold area
29	Label storage room
30	Warehouse office
31	To production
32	From production
33	Delta 0000
34	Temperature display
35	Walk path



Sampling room

Inward Entry 
 Outward Entry 

3.3. Construction and Finishes.

The building was previously owned by Sony and was used to product, Compact Discs (CDs), DVDs as well as BluRay Discs.

The basic structure was initiated in about 1992 with additions being made over the following years.

The basic office section of the overall building consists of a reinforced concrete structure and floor with gyprock or plasterboard interior partitioning.

The warehouse areas of the overall buildings consist of a steel frame to which concrete panels are attached to produce an external wall.

The roof is a metal construction with an uppermost layer of pebbles to act ballast to secure the roof as well as provide thermal stability to the area below.

The production areas use "insulation" panel as partitioning. The panel consists of fire retardant "foam", PIR (PolyIsoCyanurate) with either a painted colourbond type of cladding or a stainless steel cladding.

There are a few pre-existing panels that are constructed of EPS (Expanded Polystyrene).

The site has been fully renovated to meet the requirements of GMP Pharmaceuticals.

3.4. Heating, Ventilation, Air-conditioning (H.V.A.C.)

Heating, Ventilation, Air-conditioning (H.V.A.C.) system has been designed by Delta Air Conditioning for the production areas.

The system will consist of a central unit where air will be chilled (or heated) then passed through a HEPA (high-efficiency particulate air) filter to reduce particulates. The air will then be sent to the various production rooms.

Air will be returned (collected) from the production rooms and returned to the chiller/heater for re-use. The air will be again chilled or heated as required and passed through the HEPA filter into the air handling system.

There will be about 10 to 15% make up air. This is fresh air that is to replace air that will be lost during distribution to the production areas as well as air losses within the production areas.

There is a general requirement that rooms have a +10 Pa differential to the corridors to reduce contaminants entering the production rooms where exposed product is present.

Rooms are generally required to have a minimum of 10 air changes per minute. This rate will increase depending on the nature of the rooms use as well as the potential for exposed product to be present.

After installation the HVAC System, Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) has been evaluated as part of the equipment qualification requirement.

There are ongoing monitoring of the effectiveness and compliance of the HVAC system to ensure that it provides the optimum level of protection to products and processes.

3.5. Special (Hazardous) Area

At the current time, no toxic, hazardous or sensitising materials are used. There is however, a "dangerous goods" area which is located within the warehouse for materials that fall into the category of dangerous goods. Currently, the only material that is covered by this is ethanol and concentrated detergents.

3.6. RO Water System

Purified water is a critical service to the site. RO Water will be provided using a Vertex Hydrapore Reverse Osmosis Water System. The system is identified by model number: SLE64040 and serial number: 64040212.

After installation the RO Water System, Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) has been evaluated as part of the equipment qualification requirement.

The determined system will be capable of producing sufficient purified water to meet current needs. The chemical and microbiological specification for the water produced bases on the British Pharmacopoeia monograph for Purified Water in Bulk. On-going testing performs monthly until such time as confidence in the system permits a reduction in the frequency of the testing.

Sanitation performs on a regular weekly basis and recorded.

3.7. Preventative Maintenance and Equipment Servicing.

A preventative maintenance programme with supporting logs will be developed in conjunction with the suppliers of machinery and equipment.

There will be written procedures with service and maintenance logs for equipment and machinery. The operator's of the equipment will have reports made known to them as well as have access to the service logs or copies of important information.

3.8. Equipment.

GMP Pharmaceutical Huntingwood site has fully installed Freeze Dry Production Line. The relative major equipment includes following items: cooking vessels, aeration machine, filling machine, freezer, freeze drying units, Blender, Tablet Press, as well as a packaging line for the production of freeze-dried therapeutics and powders.

GMP Pharmaceutical Huntingwood site has fully installed a powder packaging line to pack commercial sized bulk milk powder and collagen powder in smaller consumer sized packs. This will be a food process.

GMP Pharmaceutical Huntingwood site has fully installed a tablet manufacturing line, which includes dry blender machine, tablet press machine, wet granulation machine, coating machine and encapsulation machine.

3.9. Maintenance.

The Managers of the various areas will be responsible for ensuring that maintenance is performed and documented as required. The nature of the service or repair will be determined by the nature of the situation.

Records in the form of logs are to be maintained for the various items of equipment.

3.10. Qualification, Validation and Calibration

All equipment must be suitable for the purposes for which it is employed. New equipment will undergo Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) evaluations as part of the commissioning process. Equipment already in service will undergo a similar but retrospective evaluation to ensure that it is providing the level of quality that is required.

Critical equipment such as scales or balances will be checked for performance on a monthly basis and calibrated or performance checked (certified) annually.

Other measuring equipment will be checked as specifically decided for the instrument and will be calibrated or certified as required. The time interval will be decided upon in conjunction with the certifying party.

3.11. Sanitation, Hygiene and Pest Control

There are written procedures for cleaning the various items of equipment, the cleaning agents and their concentrations that are to be used as well as the frequency. Cleaning agents such as detergents will be approved for use before being available to staff.

Sanitising agents will be selected partly based on their stability as well as efficacy. Currently, only small quantities of sanitising agents are stored to prevent efficacy problems due to aging. These will also be approved for use before being available to staff.

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There is an ongoing environmental monitoring program that requires that the various areas and air handling systems be monitored for microbiological contamination.

Cleaning and sanitation procedures are in place for the water system, air supply system and the dust extraction system with maintenance logs for documenting these procedures.

There is an ongoing pest control program with the reports prepared by the contractor being evaluated by GMP staff to determine the effectiveness of the program.

4. DOCUMENTATION

4.1. Preparation Distribution and Review of Documents

Currently, documents are being prepared using a standardised format with Microsoft Word[®]. The documents are required to be personally signed by the author, the person checking the document for errors and then the authorising person. The date of issue is then written on the document and if necessary, each page of the document is identified as a master document. No document is recognised which does not have the signatures of the author, checker, authoriser and date of issue. The issue, revision, retrieval and archiving of documentation is managed by the QA Manager or delegate.

Batch documents are initially given to the production manager or delegate after they have been issued by the Planning Department. The batch is manufactured or packaged with production staff making any necessary data entries. When completed, the Area Supervisor reviews the batch document and if satisfied, signs off. When the Production Manager is satisfied that the documentation is in order, it is given to the QA Manager or delegate to determine the disposition of the batch. The batch documents are then archived.

The QA Manager or delegate is responsible for the preparation, revision and distribution of all documentation relevant to the manufacturing and/or packaging of product.

The Master Documents are stored within the QA office of the business.

Documents concerned with the manufacturing of products are prepared and issued according to the relevant SOP and have a standardised format. There are documents for product specifications, raw material specifications, packaging specifications, approved labels and pre-printed materials, standard process instructions, batch records including packaging and QA release procedures.

A computerised inventory control system called "Pronto" is used to print out the assembly quantities of materials for either bulk manufacture or packaging and these hard copy batch documents that are to be checked for accuracy before issue. The system will not replace the current system where quarantine labels are used to identify items and approved labels to indicate their status.

The Pronto inventory system is not used for any physical status changes to materials. Status of materials is a manual process using physical labels which are applied to goods.

Documentation is controlled by the relevant SOP, which requires that all master documents be identified as such and available only to authorised personnel, who may produce and mark uncontrolled copies as required. Each master document will incorporate a distribution list of authorised copies. This list will be used when a document is reissued to retrieve all copies of the superseded version.

All documents will be maintained for a minimum of three years after they have expired or been superseded.

Currently, all documents are hard copy only and there is no plans to use electronic or microfilmed recording.

At all times, the requirements of the Code of Good Manufacturing Practice are used as a guide when documents are required and when being prepared.

5. PRODUCTION

5.1. Production Operation

The site will be capable of dispensing the materials required for and then packaging liquids, semi solid dosage and solid dosage forms as well as freeze dried products such as "mouth dissolvable tablets".

TGA license has been issued for the following:

- The manufacturing of the solid dose form: Tablet Orally Disintegrating.
- The manufacturing of the solid dose form: Tablet Chewable
- The manufacturing of the solid dose form: Tablet ,Uncoated
- The manufacturing of the Dosage Form: Powder.
- The storage of all dosage form.
- Physical Testing for all dosage form.
- Chemical Testing for all dosage form.
- microbiological Testing for all dosage form

The license for the site to manufacture food items such as dairy (milk) products for local supply and export as well as blend and re-package dairy milk powders.

TGA license has been applied for the following:

Capsule, Enteric
Capsule, Hard
Capsule, Modified release
Tablet, Effervescent
Tablet, Film coated
Tablet, Enteric coated
Tablet, Modified release
Granules.

The general procedure for the manufacture of a bulk product of all kinds is as follows:

Raw Materials are received and placed into the "Quarantine" area. The raw material has quarantine labels affixed and the delivery is documented (booked in). The raw material is sampled and a "Raw Material Result Sheet" is created for the delivery. The relevant details are entered on the Raw Material Result Sheet, which also indicates the testing required. If the raw material complies with the requirements it is then "Approved" for use by having an Approved label affixed and transferred to the main store. The packaging and labels are treated in a similar manner to the raw materials. A batch card/record is issued, which indicates the assigned batch number, for a particular product at which time the availability of the necessary raw materials is confirmed as well as the availability of the required equipment. The materials are then dispensed in accordance with the issued batch card/record. The processing of the batch is then initiated. The operator is required to enter the relevant information onto the batch card/record during the processing of the batch. At the completion of the drying/demolding stage of the batch a sample is submitted for evaluation by Quality Control. If the batch complies with the requirements it is "Approved" and an approved label is affixed to the batch at which time it is ready for filling and the labeling. The filling and the labeling stages are also controlled by the batch card/record which requires the operator to enter details. When the product is packed a reconciliation is performed on the batch. If the requirements are complied with, the product is released for further processing by the QA Manager or someone delegated to perform that function. During processing, the batch is identified by its unique identification or batch number.

If it is necessary to transfer the batch to storage containers, these containers will have "In-process Identification" labels affixed and if appropriate "Approved" labels will also be affixed.

The general procedure for packaging is as follows:

If the product is of GMP Pharmaceuticals manufacture, it will be made available to the packaging area after it has been approved and appropriate status labels affixed.

If the product has been received from another manufacturer it will be treated in the same manner as raw material and if acceptable it will be approved for use and appropriate status labels affixed. It will then be made available to the packaging area for us.

Packaging and printed matter are treated in a similar manner to raw materials.

After the various components are approved for use approved labels are affixed where required. The required batch instruction/record is issued, which indicates the assigned batch number. At this stage the required packaging materials as well as the capsules are taken to the packing room. The process capsules filling is conducted in accordance with the batch instruction/record. The batch records are given to the Production Manager or someone delegated to perform that function for initial checking to determine if the documentary requirements and the reconciliations are in compliance with the requirements. The packaging document is then reviewed by QA Manager or someone delegated for that purpose to ensure that all requirements and reconciliations are within specification and that any non-conformances and deviations are accounted for and that appropriate reports are prepared. The goods are then released for further processing or supply depending on the discretion of the QA manager or delegate.

5.2. Handling of Starting (Raw), Packaging Materials and Finished Products

Each delivery of a starting or packing material is given a unique identifying number, in the case of this company it is called a GIN number (Goods Inward Number).

The materials are sampled or inspected in accordance with the SOP for sampling.

The status of the materials is identified by labels such as Quarantine, Approved or Rejected.

Materials may only be issued if they have been approved for use.

Materials being used for manufacture are identified and released for use manually.

Where appropriate in-process checking is employed to assist in controlling the quality of the batch and when formally employed the batch documents will require that the operator record the results on the batch documents.

Line clearance checks are incorporated in the packaging/labeling instructions

Before product is permitted to leave the premises reconciliations of the bulk product and packing and labeling materials are conducted. The product is released for sale or further processing only if the results of the reconciliations comply with the requirements.

5.3. Reject Materials.

Non-conforming materials and products that have been rejected for use are clearly labeled with a "Reject" label which clearly identifies the material or product and its identification number. They are stored in a segregated area.

In the case of non-conforming raw materials they will either be returned to the supplier or disposed of as waste, whichever is appropriate. In the case of product it will be either reworked if possible or disposed of as waste again whichever is appropriate. Appropriate notations will be entered onto the log.

5.4. Process Validation

Process validation will be performed on all manufacturing processes.

6. QUALITY ASSURANCE and QUALITY CONTROL

6.1. The Quality Assurance and Quality Control System

Incoming raw materials are sampled and where required these samples are either chemically analysed internally or sent to an authorised external analyst for analysis for evaluation before approval. Internal and external laboratories will be suitably licensed or accredited. Certificates of analysis are examined against specifications. Testing results are compared against the specification before release. The source of materials is checked against an Approved Supplier List.

Incoming packing components are inspected, tested and compared to specifications before approval as well as having their source checked against an Approved Supplier List.

Incoming printed materials are inspected and compared against reference standards before approval.

Review of batch documentation, release of final documentation as well as the preparation, revision and distribution of documents is performed within the QA area.

7. CONTRACT MANUFACTURE and ASSURANCE

7.1. Contract Manufacture and Assurance

Contract Manufacture:

In the event that outside manufactures are used to provide product they are required to be licensed by the Therapeutic Goods Administration (TGA) or licensed by a third party that is approved by the Therapeutic Goods Administration (TGA).

Additionally in each case a GMP Agreement will be established between the product provider (contract acceptor) and GMP Pharmaceuticals (contract giver).

Compliance will be monitored by the use of a formalised auditing process.

Contract Analytical Testing:

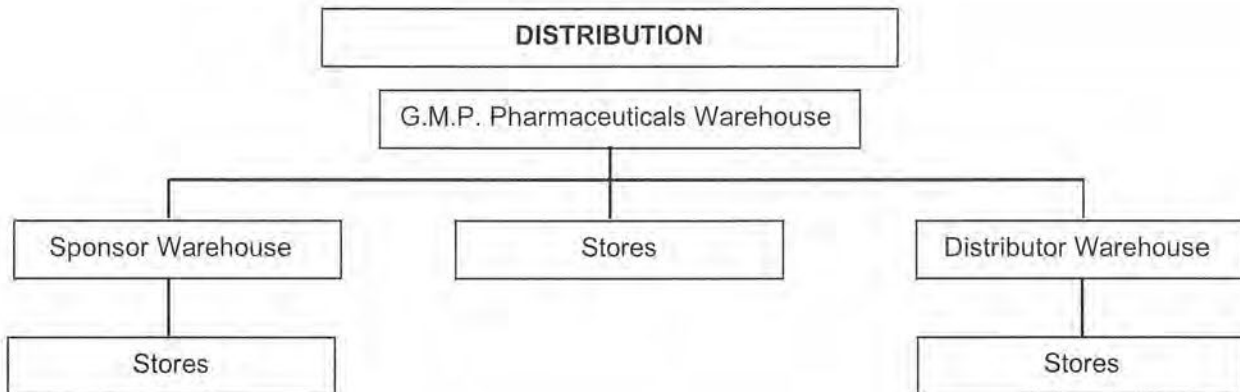
Providers of analytical support will be required, wherever possible, to be licensed by the Therapeutic Goods Administration (TGA) as well as being NATA Registered.

Additionally, in each case of a therapeutic product a GMP Agreement will be established between the product provider (contract acceptor) and GMP Pharmaceuticals (contract giver).

8. DISTRIBUTION, COMPLAINS AND PRODUCT RECALL

8.1. Distribution

The warehouse is a secure location, but is not environmentally controlled. There is refrigerated storage available. Materials are stored using pallet racking with their status being identified by the use of labels. Bin locations are also used to locate materials.



8.2. Complaints and Product Recall

The retained records permit full traceability of product manufactured and delivered to customers. The date of supply, the customer details and the quantity despatched as well as the batch numbers are recorded.

A written SOP is used to deal with complaints with the QA Manager or delegate being responsible for the procedure including, logging, classifying and investigating the complaint. Written reports are maintained for each complaint with the reports being reviewed initially by the QA Manager or delegate and then the General Manager. These reports will be maintained for a minimum of three years. There will be an annual report circulated to all managers that details the complaints received.

A written SOP is in place which deals with product recalls and which includes retrieval of distribution data, notification of customers, the receipt/ segregation/ inspection of returned product, investigation/ reporting of cause and reporting corrective action.

The QA Manager or delegate records and analyses product complaints and is responsible for notifying the Competent Authority (the TGA) of a potential recall situation as well as for co-ordinating an actual recall.

Although detailed batch records are not generally maintained by the various sponsors and distributors, it is believed that the information available would be sufficient to effectively enable a recall of a very significant quantity of product at batch level.

9. SELF-INSPECTION

9.1. Self-Inspection System

Self-Inspection is performed on a regular basis as per an internal auditing programme with the objective to ensure that all business operations are in compliance with SOP and regulatory requirements. Reports on the audits are written and brought to the attention of the appropriate manager and a written reply is required. A compliance record is maintained with any undertakings and times for remedial action in the reply.

The quality systems currently in place are effective for the products that are currently manufactured.

The internal auditing system and the requirement for the documentation of follow-up actions are covered by a SOP.

10. FUTURE DEVELOPMENTS

10.1. Future Developments

While it is not possible at any stage to state that a specific event, requirements, policies, practices, procedures or capabilities will be in place at some stage in the future it is possible to give an indication of what the company has as an intention.

10.2. Site Development

The Company has acquired the site with the intention of renovating it to be able to manufacture and pack tablet and repack dairy milk powders for export. It is intended to have testing facilities NATA registered.

10.3. Therapeutic (TGA).

An application has been made for Therapeutic Goods Administration (TGA) licensing for:

- The manufacturing of the
- Capsule, Enteric
- Capsule, Hard
- Capsule, Modified release
- Tablet, Effervescent
- Tablet, Film coated
- Tablet, Enteric coated
- Tablet, Modified release
- Granules

10.4. Therapeutic (APVMA).

The company does not have an APVMA license for this site. The company has no plans to apply for an APVMA license but if they do it will only manufacture products that are consistent with the TGA license.

10.5. Food (NSW Department of Primary Industry and Biosecurity)

There are plans to prepare various other freeze dried dairy based products and pack them.

10.6. Department of Agriculture

It is expected that production of dairy products will be established in the near future based on Commonwealth Department of Agriculture export registration.

10.7. Other Products and Services

The company is considering what other products or types of products may be considered for manufacture, provided that they do not have any effect on the therapeutic or food products.

GMP Pharmaceuticals Pty. Ltd.
SITE MASTER FILE
60 HUNTINGWOOD DRIVE

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PUBLICATION AND REVISION HISTORY

Issue Date	Document Reference	Change No.	Details of Change	Previous Version	Current Version
August 2019	Site Master File No. 60 Huntingwood Drive	New	New	New	001
January 2020	Site Master File No. 60 Huntingwood Drive	CC20001	Update details for NSW food licence, organisation structure Updated document Number	001	002
February 2021	Site Master File No. 60 Huntingwood Drive	CC21007	Update details for TGA licence, Personnel Change, Production Status, Equipment and Facility Update and Future Plan.	002	003
November 2021	Site Master File No. 60 Huntingwood Drive	CC21060	Update drawings in the file and Licence	003	004
13 th April 2022	Site Master File No. 60 Huntingwood Drive	CC21065	Updated dosage forms. Update drawings and organization chart in the file	004	005

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Career Objective:

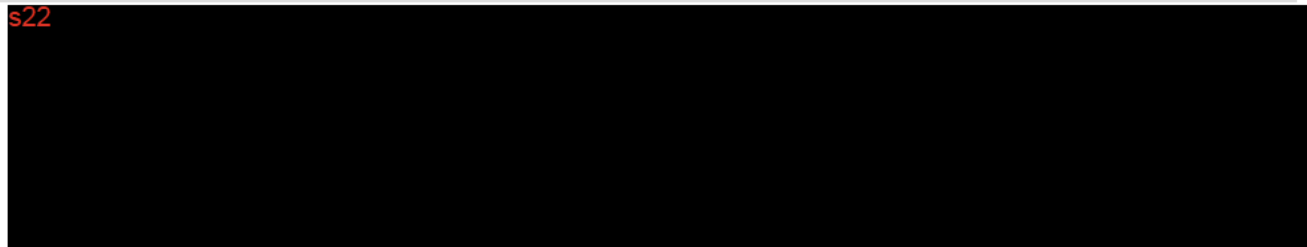
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Work Experience:

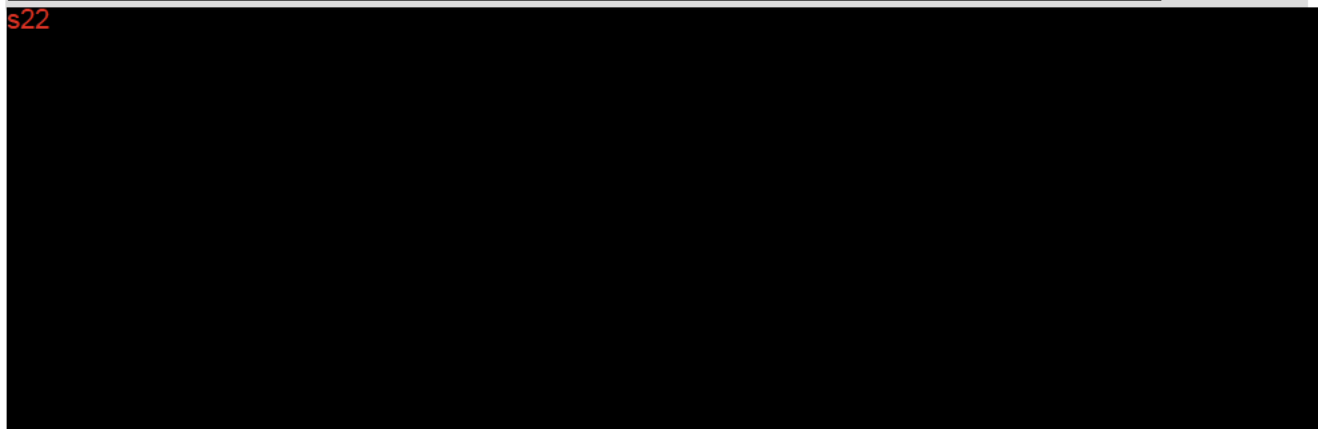
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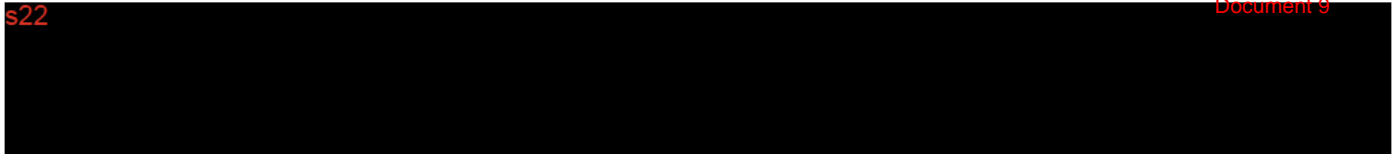


Technical & Computer skill:



Educational Qualification:





Other Skills:



Referee: Can be provided based on request