



Australian Government

Department of Health

Therapeutic Goods Administration

Release for supply of medicines

Technical guidance on the interpretation of the PIC/S Guide to GMP

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TGA Health Safety
Regulation

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About this guidance

This guidance is for TGA licensed or certified manufacturers and Australian sponsors of a medicine manufactured under the [PIC/S Guide to GMP for medicinal products](#) (PIC/S Guide to GMP). This guidance outlines:

- our interpretation of release for supply (RFS) of medicines in Australia
- your responsibilities related to RFS of medicines
- the role of an authorised person in RFS of medicines

We provide additional guidance on RFS requirements when [releasing medicines manufactured at multiple sites](#).



RFS by an authorised person in Australia is different from the European system of batch certification by a Qualified Person. The European system is not adopted in the Australian [manufacturing principles](#).

However, a Qualified Person meets the definition of an authorised person within the Australian regulatory framework.

All **finished** product batches manufactured according to the PIC/S Guide to GMP are required to comply with release for supply requirements.

Medicines that need to comply with RFS

This guidance on RFS applies to the following **medicines**:

- ✓ all medicines on the ARTG:
 - listed medicine
 - registered medicines
 - export-only medicines
 - medicinal gases – additional information available in Medicinal gas guidance – release for supply
 - biological medicines – such as vaccines and biotechnology products.
- ✓ investigational medicinal products that are used in clinical trials in Phase 2 onwards.
- ✓ extemporaneously compounded medicines.



References in this guidance to **market authorisation** and ARTG entries **do not apply** to products that are exempt from inclusion in the ARTG, such as:

- investigational medicinal products (need to comply with the Product Specification File)
- compounded medicines

This guidance document is applicable to investigational medicinal products, subject to any difference in the legal provisions and more specific guidance in Annex 13 of the PIC/S Guide to GMP.

This guidance **does not apply** to:

- ✘ [Medical devices](#)
- ✘ the manufacture of active pharmaceutical ingredients (APIs)
- ✘ medicines prepared for initial experimental studies in human volunteers (Phase 1 clinical trials) as these are exempted from GMP
- ✘ products covered under the [regulatory framework for biologicals](#); additional information is provided in [manufacturing biologicals](#)
- ✘ specific requirements for biological medicines under Official Control Authority Batch Release.

Development of this guidance

This guidance was developed in collaboration with industry and explains TGA's interpretation and expectations for compliance with the release for supply requirements of the PIC/S Guide to GMP.

This information is provided for **guidance only** and has been developed on the basis of current knowledge of the subject matter. It should not be relied upon to address every aspect of the relevant legislation. Please also refer to the [Therapeutic Goods Act 1989](#) and the [Therapeutic Goods Regulations 1990](#) for legislative requirements and the current version of the [PIC/S Guide to GMP](#).

Disclaimer

This guidance is not mandatory or enforceable under law. It is not intended to be restrictive. We recommend following this guidance document to facilitate regulatory obligations being met. The guidance describes a way that a manufacturer may operate to demonstrate compliance with the relevant manufacturing principles (PIC/S Guide to GMP).



Guidance documents are not intended to establish a minimum standard of practice for inspection purposes. Guidance documents are not enforceable.

Sections of PIC/S guide to GMP that apply to the RFS process

All relevant clauses of the PIC/S Guide to GMP apply to the manufacture of medicines. This document provides specific guidance regarding the interpretation of certain GMP requirements. Where we do not provide any commentary regarding interpretation, we expect the manufacturer to comply fully with those requirement(s), without further interpretational guidance.

In general, manufacturers should follow the principles of Part I of PIC/S guide, and in addition, all annexes relevant for release for supply and release for further processing to the next manufacturer in the supply chain.

Related guidance

Due to the range of medicinal products regulated in Australia and the detail required for different classes of products, additional guidance is provided for the following aspects that contribute to, or are related to, RFS:

- [TGA interpretation and expectations for demonstrating compliance with PIC/S PE009-13](#)
Understand our interpretation and expectations for compliance with specific sections of the *PIC/S Guide to Good Manufacturing Practice for Medicinal Products*, PE009-13
- [Medicinal gases](#)
Understand our expectations for medicinal gas manufacture.
- [Product quality reviews \(PQR\)](#)
For listed and complementary medicines, understand how to produce a PQR and your responsibilities.
- [Ongoing stability programs](#)
For listed and complementary medicines, understand the requirements and your responsibilities for ongoing stability programs.
- [Risk classification for manufacturers](#)
Understand how we classify levels of risk based on the manufacturing processes used at different sites and how this impacts our approach to inspection frequency.

About release for supply (RFS)

Release for supply is defined in the PIC/S Guide to GMP, clause 1.4 xv, as:

Certification by an authorised person 'that each production batch has been produced and controlled in accordance with the requirements of the Marketing Authorisation and any other regulations relevant to the production, control and release of medicinal products.'

Release for supply is:

- verification that all production and quality control testing records of a batch comply with Chapters 2 and 3 of the *Therapeutic Goods Act 1989*
- mandatory for medicinal products manufactured according to GMP
- the last manufacturing step
- a licensable step in manufacture within Australia
- performed through a legally valid signature of an authorised person

Australian RFS requirements

Before releasing any finished medicinal product for supply in Australia, an authorised person must certify that **each** batch has been manufactured and controlled in accordance with:

- marketing authorisation requirements, where applicable
- other regulations relevant to the production, control and release of the product.

For therapeutic goods with a marketing authorisation, do not take anything in this guidance as overriding the arrangements for the marketing authorisation.

Relevant authorisation and standards

RFS focuses on compliance with the following authorisations and standards:

1. all aspects of the marketing authorisation, including:
 - a. all details in the ARTG
 - b. all other matters in relation to the marketing authorisation agreed in writing between the TGA and the Australian sponsor (e.g. variations to the ARTG entry, S14 Exemptions from compliance with a standard)
2. for domestic manufacturers: the licence to manufacture therapeutic goods, including:
 - a. the authorisations and conditions under the licence
 - b. the steps in manufacture granted under section 38, *Therapeutic Goods Act 1989*
 - c. conditions of licences as imposed under section 40, *Therapeutic Goods Act 1989*
3. for overseas manufacturers: the TGA GMP certificate or GMP clearance(s), specifically their authorisations and conditions, as imposed under:
 - a. sections 25(1)(g) and 26(1)(g), *Therapeutic Goods Act 1989*
 - b. section 26A(3), *Therapeutic Goods Act 1989*
4. the PIC/S Guide to GMP as specified in the current [manufacturing principles](#).
5. [default standards](#) under Section 10, *Therapeutic Goods Act 1989*
6. all applicable [Therapeutic Goods Orders](#) (TGOs)
7. all relevant GMP requirements, including assessing:
 - a. Product Quality Reviews
 - b. effectiveness of the on-going stability program

Scope of supply

Supply does not only consist of sale within Australia.



Supply includes:

- sale within Australia
- other forms of supply within Australia, such as:
 - free samples
 - investigational medicines for use in phase 2 onward clinical trials
- export from Australia

Authorised person definition

An authorised person is a person recognised by the authority as having the necessary basic scientific and technical background and experience. Authorities identify who the authorised persons are through the manufacturer's pharmaceutical quality system.

Authorised person(s): an employee or employees authorised by a TGA approved manufacturer through a statement in the manufacturer's pharmaceutical quality system to perform release for supply. The person nominated to have control of quality control under section 37(1)(e), *Therapeutic Goods Act 1989* would be an obvious choice to be an authorised person, but other arrangements can be considered, including delegation.

Authorised person responsibilities

The authorised person certifies:

'that each production batch has been produced and controlled in accordance with the requirements of the Marketing Authorisation and any other regulations relevant to the production, control and release of medicinal products' (PIC/S Guide to GMP, clause 1.4 xv).

The authorised person taking responsibility for release for supply is to:

1. have full access to, and detailed knowledge of all the following authorisations and standards:
 - a. marketing authorisation, including details in the ARTG and other matters agreed on in writing between TGA and the Australian sponsor
 - b. [PIC/S Guide to GMP](#) as defined in the manufacturing principles (for domestic sites), or at least equivalent for overseas sites
 - c. [default standards](#), where they apply
 - d. all applicable [Therapeutic Goods Orders](#)
2. complete all [duties of an authorised person](#)
3. provide a legally valid signature for every batch released
4. have detailed knowledge of the steps in manufacture for which responsibility is taken
5. keep their knowledge up to date, in accordance with the [PQS](#), in light of both:
 - a. technical and scientific progress
 - b. changes in quality management relevant to the products they release
6. have access to appropriate information to consider the release for supply results within the context of both:
 - a. product quality review (PQRs) findings
 - b. ongoing stability program data

Duties of an authorised person performing RFS

Before release of a production batch for supply, the authorised person is responsible for ensuring:

1. each batch has been produced and controlled in accordance with all the requirements of:
 - a. any marketing authorisations (item 7, clause 1.9, Part 1 of the [PIC/S Guide to GMP](#)), including:
 - i. all details in the ARTG
 - ii. all other details agreed in writing between the TGA and the Australian sponsor in relation to the marketing authorisation
 - b. any other regulations relevant to the production, control and release of the therapeutic good manufactured under GMP (item xv, clause 1.4, Part 1 of the [PIC/S Guide to GMP](#))
 - c. the [PIC/S Guide to GMP](#) for domestic manufacture or if manufactured overseas, in accordance with good manufacturing practice standards, at least equivalent to the [PIC/S Guide to GMP](#)
2. all manufacturers involved in producing the batch are to:
 - a. hold a TGA licence or be covered by a current GMP clearance for all of the manufacturing steps they have performed
 - b. be included in the ARTG entry for the manufacturing steps performed
 - c. have the services of at least one authorised person available at each site
 - d. have any partial manufacturers or outsourced activities covered by valid [GMP agreements](#) in accordance with chapter 7 of the [PIC/S Guide to GMP](#)
3. all processes have been fully validated, taking into account the actual production conditions, manufacturing and test records for the:
 - a. principal manufacturing processes
 - b. release testing processes (as per finished medicinal product specifications)
4. all necessary production and quality control documentation is complete and approved by authorised staff, including out-of-specification (OOS) investigations
5. all the necessary checks and tests have been performed; including any additional sampling, inspection, tests or checks initiated due to deviations or planned changes
6. product quality reviews have been performed in a timely manner and are accurate
7. any significant deviations or planned changes in production or quality control have been:
 - a. authorised by the persons responsible in accordance with a defined system
 - b. notified to and authorised by TGA if any changes require variation to the marketing authorisation, manufacturing licence or GMP clearance
8. all necessary steps have been completed in accordance with the pharmaceutical quality system (PQS), regardless of how many sites are involved
9. GMP internal audits and supplier audit systems are operational

10. check that the shelf life is supported by the available ongoing stability data, as described in [Releasing medicines manufactured at multiple sites](#)
11. any other factors of which the authorised person is aware, which are relevant to the quality of the intermediate product, bulk and finished product batch, have been considered, such as:
 - a. significant deviations
 - b. out-of-specification results
 - c. non-compliance with GMP
 - d. investigations
 - e. complaints
 - f. other related matters throughout production from all manufacturing sites
12. The authorised person may delegate tasks to appropriately trained personnel or third parties to verify the RFS requirements have been met. We recognise that the authorised person will need to rely on a pharmaceutical quality system (PQS), so the authorised person should have on-going assurance that this reliance is well founded.
13. Where release for supply involves multiple manufacturing sites, be aware of your [additional responsibilities](#)



While investigational medicines do not have a marketing authorisation, consistent with Annex 13, they need to be produced in accordance with the principles and the detailed requirements of the PIC/S Guide to GMP.

Sponsor RFS responsibilities

As the sponsor (the market authorisation holder), your responsibilities related to release for supply include:

- [sharing information with a contracted manufacturer or authorised person](#)
- shared responsibilities with the manufacturer include:
 - [ability to recall a batch](#)
 - [GMP agreements](#)
 - [ongoing stability data and updates](#)
 - [product quality reviews](#)
 - [provide authorised person\(s\) access to information](#)

[Sponsors wanting to conduct RFS](#) have additional responsibilities.

Sponsors also need to share all relevant information in the marketing authorisation with all manufacturers in the supply chain.



Licensing and certification guidance:

- [GMP clearance guidance](#)
Information for sponsors seeking to obtain GMP clearance for an overseas manufacturing site
- [Sponsor responsibilities related to GMP clearance and certification](#)
Guidance on sponsor's responsibilities when supplying medicines manufactured overseas.
- [Australian manufacturing licences and overseas GMP certification](#)
Information for Australian manufacturers seeking TGA licence or Australian sponsors applying for GMP certification of overseas manufacturers

Sharing information with a contracted manufacturer or authorised person

RFS is a licensable step in manufacture within Australia. This requires the manufacturer performing RFS to have access to the relevant information in the marketing authorisation, where applicable.

If you are reluctant to share this information with a (contract) manufacturer performing RFS, for example due to confidentiality issues, you could do one of the following:

- implement a confidentiality agreement with the manufacturer, or include confidentiality statements in the GMP agreement
- contract out the RFS manufacturing step to a different manufacturer who holds the relevant licence, GMP clearance or GMP certification
- obtain a [TGA licence to act as manufacturer yourself for the RFS step](#)

You can consider alternative options as long as they do not impede prompt recall and access to data required for compliance to regulatory requirements and responsibilities.

You can only contract out release for supply to an independent authorised person if the authorised person holds or works under a TGA licence or a current GMP clearance that includes release for supply.

Sponsors wanting to conduct RFS

Release for supply is a manufacturing step that requires a TGA licence. If a sponsor wants to perform release for supply they must:

- hold a TGA manufacturing licence
- be authorised within the marketing authorisation for that step in manufacture
- meet the responsibilities of a release for supply manufacturer

Sponsor and manufacturer – joint RFS responsibility

The PIC/S Guide to GMP identifies shared responsibilities between the sponsor (marketing authorisation holder) and the manufacturer, including:

- [ability to recall a batch](#)
- [GMP agreements](#)
- [ongoing stability data and updates](#)
- [product quality reviews](#)
- [provide authorised person\(s\) access to information.](#)

Ability to recall a batch

A system needs to be available to identify and recall any batch of medicine from sale or supply without delay, for all products that could be rendered hazardous by a quality defect in the batch.

GMP Agreements

Sponsors and manufacturers are required to establish valid GMP agreements, in accordance with the [PIC/S Guide to GMP](#), including:

- clearly establishing responsibilities for all GMP related activities
- specifying how the RFS authorised person ensures that each batch has been manufactured and checked for compliance with the marketing authorisation, where applicable.

Where multiple manufacturers are involved in the manufacture of a product, there are additional details regarding the contents of GMP agreements (including ongoing stability and product quality review arrangements) in:

- [Releasing medicines manufactured at multiple sites](#)

If the multiple manufacturers are part of one organisation and are covered by the same corporate quality system, responsibilities for RFS could be clearly defined within the corporate quality system, instead of having separate GMP agreements between sites.

Ongoing stability

The RFS manufacturer and, where different, the sponsor, are responsible for ensuring:

- an on-going stability program is performed
- the on-going stability results are reviewed to monitor product stability
- the ongoing stability results are provided promptly to the authorised person that performs RFS

Related guidance on ongoing stability

We cover the principles of conducting ongoing stability studies in:

- [TGA interpretation and expectations for demonstrating compliance with PIC/S PE009-13](#)

For listed and complementary medicines, additional guidance is available:

- [Ongoing stability testing for listed and complementary medicines](#)
- [Sunscreen manufacturing, Demonstrating compliance with the PIC/S guide to GMP, PE009-13](#)

Product quality reviews

The manufacturer and, where different, sponsor (market authorisation holder), are responsible for ensuring:

- the PQR is performed and prepared in a timely manner, and is accurate
- the PQR results are reviewed and evaluated to assess if corrective and preventive actions, or any revalidation, should be undertaken under the PQS

Related guidance on PQRs

We outline the expectations of all manufacturers of medicines to generate PQRs in accordance with GMP requirements, in:

- [TGA interpretation and expectations for demonstrating compliance with PIC/S PE009-13](#)

For listed and complementary medicines, additional guidance is available:

- [PQRs for listed and complementary medicines](#)

Provide authorised person(s) access to information

The manufacturer and, where different, sponsor, are responsible for ensuring the authorised person(s) responsible for RFS have full access to:

- all aspects of the marketing authorisation, including details in the ARTG and other matters agreed on in writing between TGA and the Australian sponsor
- all relevant aspects of the manufacturers and manufacturing steps:
 - for TGA-licensed manufacturers:
 - the licence to manufacture therapeutic goods
 - all authorisations and conditions under the licence
 - the steps in manufacture granted under section 38, *Therapeutic Goods Act 1989* and conditions of licences as imposed under section 40, *Therapeutic Goods Act 1989*
 - for overseas manufacturers:
 - the TGA GMP certificate and GMP clearances

- all authorisations and conditions, as imposed under sections 25(1)(g), 26(1)(g) and 26A(3), *Therapeutic Goods Act 1989*
- the PIC/S [Guide to GMP](#) as specified in the current manufacturing principles
- [default standards](#) under section 10 of the *Therapeutic Goods Act 1989*
- all applicable [Therapeutic Goods Orders](#)
- relevant batch certificate of analysis
- complete and **reviewed** PQRs
- ongoing stability data and updates
- significant batch deviations
- approved artwork specifications
- significant changes to manufacturing processes and ongoing validation:
 - product release and expiry specifications
 - marketplace feedback or signals
 - complaints, recalls, adverse events
 - supply chain details and approved manufacturers and suppliers (all contracts)
- Transport arrangements and any transport data that is available



Responsibilities for providing authorised person(s) access to information when performing release for further processing (RFFP) are covered in the guidance [Releasing medicines from multiple manufacturing sites](#).

Manufacturer RFS responsibilities

In addition to ensuring manufacturing is compliant with any marketing authorisations, all RFS manufacturers, both in Australia and overseas, are responsible for the following:

- [Traceability of each batch](#)
- [Appointing authorised person\(s\)](#)
- [Pharmaceutical quality system](#) (PQS)
- [Shared responsibilities with the sponsor](#)
 - [Ability to recall a batch](#)
 - [GMP agreements](#)
 - [Provide authorised person\(s\) access to information](#)

[Overseas manufacturers](#) can perform release for supply, provided certain conditions are met.

Related guidance on manufacturing

[Australian manufacturing licences and overseas GMP certification](#)

A step-by-step guide for Australian manufacturers wanting to apply for a manufacturing licence and overseas manufacturers inspected by TGA

[Manufacturing medicines and biologicals for use in a clinical trial](#)

This guidance is part of the *Australian clinical trials handbook* and explains the requirements of both local and overseas manufacturers producing medicinal products for use in clinical trials.

[Releasing medicines manufactured at multiple sites](#)

Additional information on GMP requirements when releasing products manufactured at multiple sites.



Manufacture in different locations

Manufacture, including quality control testing, of a batch of medicines takes place in stages, which may be conducted at different sites and by different manufacturers located either within Australia or overseas. In all cases, each stage should be conducted in accordance with the requirements outlined in the [duties of an authorised person](#).

Traceability of each batch

Ensure documentation provides traceability of each batch according to the basic requirements of GMP including records of manufacture which:

- demonstrate all required steps were performed and that the quantity and quality of the product was as expected
- fully record any significant deviations, including investigation and appropriate corrective and preventive actions implemented
- enable the complete history of a batch to be traced by being retained in a comprehensible and accessible form

Review the batch records to ensure that the release for supply site and authorised person are identifiable when the product ARTG entry allows more than one release for supply site.

Appointing authorised person(s)

RFS authorised persons are key personnel (clause 2.5, Part 1, [PIC/S Guide to GMP](#)) and may be:

- the person(s) nominated to have responsibility for quality control by an Australian manufacturer under section 37(1)(e), *Therapeutic Goods Act 1989*
- another specified person, or a delegate

A manufacturer may have more than one authorised person for RFS:

- all authorised persons:
 - should have the necessary qualifications and practical experience
 - would normally be full-time personnel

- each manufacturing site (whether in Australia or overseas) must have at its disposal the services of at least one authorised person (for RFFP and/or RFS)

In the PQS, you are to clearly document and explain the authorised person's job functions and training relating to release.

Pharmaceutical quality system (PQS)

Your PQS is to be compliant with the PIC/S Guide to GMP and needs to include:

- detailed release procedures
 - if computer systems are used to record RFS decisions, take note of Annex 11 of the PIC/S Guide to GMP
- details of the authorised person(s) responsible for release for supply
- training arrangements that ensure the authorised person:
 - has a level of education and expertise appropriate for the steps in manufacture for which responsibility is taken
 - is proficient in the release for supply requirements of the PQS
 - has appropriate knowledge for the specific steps in manufacture for which responsibility is taken
 - keeps their knowledge up-to-date in light of:
 - technical and scientific progress
 - changes in quality management relevant to the release that they authorise

Overseas manufacturers

We recognise release for supply by an authorised person located at an overseas manufacturer, provided all of the following conditions are met:

- the manufacturing steps performed are covered by a current TGA GMP certificate and/or GMP clearance(s), specifically their authorisations and conditions, as imposed under sections 25(1)(g), 26(1)(g) and 26A(3) of the *Therapeutic Goods Act 1989*
- responsibilities for RFS are clearly defined in either:
 - a GMP agreement between the contract giver (which can be the sponsor or a manufacturer) and the contract acceptor (RFS manufacturer)

OR, if both are part of one multinational organisation and are covered by the same corporate quality system:

- an arrangement within the corporate quality system
- nominated in the ARTG entry that RFS is being performed by the overseas manufacturer

Our [GMP clearance guidance](#) outlines details regarding overseas manufacturer's responsibilities.

We assess and verify release for supply arrangements with overseas manufacturers through either:

- an on-site GMP inspection

- the compliance verification process (except when compliance verification is based on evidence from MRA regulators in their own country)

We assess:

- the GMP agreement(s) with the contract givers
- the RFS procedures including marketing authorisation requirements

The RFS process

Before signing the release for supply certification, it is the responsibility of the RFS authorised person to ensure all manufacturing stages comply with the GMP requirements. We have presented a list of stages to help clarify the RFS requirements.

The stages presented are not in a specified order.

For completeness, information has been included to cover:

- all medicines, which refers to [medicines that need to comply with RFS](#) (as described in this document)
- additional requirements for those medicines on the ARTG
- additional requirements for complex supply chains where manufacturing occurs at multiple sites

For all medicines that need to comply with RFS, obtain and review the information described below and any other relevant information.

GMP of manufacturer(s)

For **all medicines** check that the manufacturer:

- holds a current TGA-licence or GMP-clearance
- all relevant manufacturing steps are covered

For a **medicine on the ARTG**, check:

- that the manufacturer of the batch is included in the ARTG entry
- if the medicine is also manufactured at multiple manufacturing sites, check each manufacturer and partial manufacturer are included in the ARTG entry

For a medicine manufactured at **multiple manufacturing sites**, check:

- all manufacturers (and partial manufacturers) of the batch hold a current TGA-licence or GMP-clearance
- all relevant manufacturing steps are covered by the appropriate licence or clearance

GMP agreements

For **all medicines** check that valid GMP agreements are established in accordance with [PIC/S Guide to GMP](#) between the sponsor (market authorisation holder) and manufacturer, where they are different entities.

For a medicine manufactured at **multiple manufacturing sites**, check that a valid GMP agreement is in place for all manufacturers and partial manufacturers, in accordance with [PIC/S Guide to GMP](#).

Acceptability of PQS

Where manufacturing occurs at **multiple sites**:

- check that an appropriate PQS describes all manufacturing steps - you might do this by accepting the PQS through the supplier qualification program
- ensure that you have ongoing assurance that your reliance on their PQS is well founded
- check that the GMP internal audits and supplier audit systems of the manufacturers are operational

Validating processes

For **all medicines**, check that the principal manufacturing and release testing processes (as per finished product specifications) have been validated taking into account actual production conditions, manufacturing and test records.

Batch records

RFS involves verification of all production and quality control testing records of a batch.

Batch production and testing

For **all medicines**:

- Check that all the necessary checks and tests have been performed, including any additional sampling, inspections, tests or checks initiated because of deviations or planned changes.
- Check all production and quality control documentation has been completed and endorsed by staff authorised to do so, including out-of-specification (OOS) investigations for quality control documentation.
- Take into account any transport data that are available.
- Take into account any other factors that you are aware of relevant to the quality of the batch.
- Check both production and controls for each batch comply with:
 - the TGA-adopted version of the PIC/S Guide to GMP (TGA-licensed manufacturers)
 - manufacturing standards at least equivalent to the PIC/S Guide to GMP (overseas manufacturers)

For **medicines on the ARTG**:

- Check both production and controls for each batch comply with the **market authorisation**, where applicable.

Traceability

For **all medicines**, ensure traceability of each batch:

- Make sure that it is easy to identify all products in a batch, so that if there is a quality defect in the batch it will be possible to recall all affected products without delay.
- Check that the following information is easy to find in the batch documentation:
 - the RFS site
 - the name of the RFS authorised person

Deviations and changes

For **all medicines**:

- Check that any significant deviations or planned changes in production or quality control have been authorised by the persons responsible in accordance with a defined system.
- Check that the TGA has authorised any changes requiring variation to the:
 - marketing authorisation, for medicines in the ARTG
 - manufacturing licence, for TGA-licensed manufacturers
 - GMP clearance, for overseas manufacturers

Product quality review and stability testing

For **all medicines**:

- Consider whether all relevant issues raised in the PQR have been adequately addressed for the batch being released.
- Check that the shelf life is consistent with the available stability data.

Signature

For **all medicines**:

- Certify release for supply with a legally valid signature of the RFS authorised person.
- Make sure the signature is dated.

Assessment of RFS arrangements during TGA inspections

TGA inspectors assess and verify RFS arrangements.

During inspections, we require access to certain information to help determine compliance with the PIC/S guide to GMP. This information below is:

- ✘ not an exhaustive list of what we will assess
- ✔ outlines some of the information you will be required to make available to us.

Authorised person

During an inspection we will verify that the manufacturer has ensured the authorised person's level of education and expertise is appropriate using the training arrangements in the manufacturer's pharmaceutical quality system.

Product quality reviews

PQRs are expected to be available for review during TGA on-site GMP inspections of manufacturers responsible for performing release for supply.

Release for further processing

During GMP inspections of (contract) manufacturers performing manufacturing steps prior to release for supply, but not the actual release for supply itself, the PQR data relevant to that manufacturing step submitted to the manufacturer performing release for supply are expected to be available for review.

Ongoing stability program

During an inspection of the RFS manufacturer, ongoing stability data are expected to be available for review. This could be by:

- staff at the RFS site requesting the data
- direct transfer of the data to the TGA inspector, if there are confidentiality issues.

Where manufacturing occurs across multiple sites, a clear mechanism to make the requested data available to inspectors needs to be detailed in your GMP agreement.

Overseas manufacturers

Overseas manufacturers are assessed and verified through on-site GMP inspection and/or the Compliance Verification (CV) process, except for CVs based on evidence from MRA regulators in their own country. These assessments are done via the GMP agreement(s) with the contract givers and involve the assessment of the release for supply procedures, including marketing authorisation requirements.

Version history

Version	Description of change	Author	Effective date
V1.0	Draft open for industry consultation	Office of Manufacturing Quality	03/06/2013
V2.0	Revised original publication: <i>Guidance on release for supply – for medicinal product manufacturers</i>	Office of Manufacturing Quality	21/01/2015
V2.1	Added link to Part 2 Guidance document for release for supply	Manufacturing Quality Branch	25/05/2016
V3.0	Restructured document Updated to be consistent with PE009-13	Manufacturing Quality Branch Regulatory Guidance Team	February 2019

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