Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Transition to new GMP requirements for medicinal products

A notice about the implications of adopting the PIC/S Guide to GMP PE009-17

Version 1.0, August 2025

Contents

Purpose

This document is for Australian sponsors and manufacturers of sterile medicines and active pharmaceutical ingredients (APIs) made or supplied in Australia. It provides a summary of the changes in GMP requirements resulting from the recent replacement of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products PE 009-16, 1 February 2022, with PE 009-17, 25 August 2023.

This notice is being issued to assist with the transition period. It is a point-in-time document and we are not planning on updating this notice.

We will be updating GMP guidance during 2025 to reflect the new requirements.

Changes to the PIC/S Guide to GMP

From 1 September 2025 the PIC/S Guide to GMP version 17 applies to the manufacture of medicines, APIs and sunscreens, unless exempt under provisions in the *Therapeutic Goods Act 1989* (the Act).

The only changes resulting from the adoption of version 17 of the PIC/S Guide relate to updates to Annex 1 for the manufacture of sterile medicinal products. All other aspects of the GMP guide remain the same.

The majority of updates to Annex 1 clarify existing GMP regulatory expectations. However, some manufacturers may need to implement and/or modify operational processes and procedures to maintain compliance following these updates. These changes are identified in the summary of new and amended requirements tables.

New and amended GMP requirements

The following summary of the amended GMP requirements provides details of the more significant differences between the PIC/S Guide to GMP PE009-16 and the PIC/S Guide to GMP PE009-17. These changes may require some manufacturers to implement or modify processes to provide improved or more detailed evidence of compliance.

See the PIC/S website for the complete PIC/S Guide to GMP PE009-14 to determine the impact on your operations and to assist in formulating your approach to implementing changes necessary because of changed requirements.

There is a 6-month transition period for adoption of these additional requirements of the new Annex 1 to allow manufacturers to review and make necessary operational changes.

Summary of new and amended requirements

The table below provides a summary of the main changes to GMP requirements for Annex 1 – Manufacture of sterile medicinal products. and our assessment of the impact of the changes.

Annex 1 new or amended requirements

New or amended requirement	Remarks
2 Principle 2.1 The manufacture of sterile products is subject to special requirements in order to minimize risks of microbial, particulate and endotoxin/pyrogen contamination. The following key areas should be considered: i. Facility, equipment and process should be appropriately designed, qualified and/or validated and where applicable, subjected to ongoing verification according to the relevant sections of the Good Manufacturing Practices (GMP) guide. The use of appropriate technologies (e.g. Restricted Access Barriers Systems (RABS), isolators, robotic systems, rapid/alternative methods and continuous monitoring systems) should be considered to increase the protection of the product from potential extraneous sources of endotoxin/pyrogen, particulate and microbial contamination such as personnel, materials and the surrounding environment, and assist in the rapid detection of potential contaminants in the environment and the product. ii. Personnel should have adequate qualifications and experience, training and behaviour with a specific focus on the principles involved in the protection of sterile product during the manufacturing, packaging and distribution processes. iii. Processes and monitoring systems for sterile product manufacture should be designed, commissioned, qualified, monitored and regularly reviewed by personnel with appropriate process, engineering and microbiological knowledge. iv. Raw materials and packaging materials should be adequately controlled and tested to ensure that level of bioburden and endotoxin/pyrogen are suitable for use.	This new clause provides additional details as to the design, qualification and control of key aspects of the facility, equipment, personnel and monitoring. Items (i) and (iii) are new clauses emphasising the importance of appropriate facility and equipment design in achieving product quality. A new requirement introduced by these clauses is the application of appropriate and contemporary technologies in the production of sterile goods which should be considered by the manufacturer. The TGA's application of this requirement would be that manufacturers would be generally expected to work towards the adoption of these technologies especially during the construction or modification of facilities. However, the TGA would consider cogent and science-based justifications for the continued use of existing legacy equipment. The adoption of appropriate and contemporary technologies has been observed consistently across Australia and the globe, especially for the design and building of new facilities, and following refurbishment, hence this new clause aligns with existing industry trends. Existing facilities with compliant, appropriately designed processes and equipment are unlikely to require significant updates to quality-risk-management procedures. Existing facilities with inappropriately designed processes should, in the first instance, re-assess these items for risk, and implement appropriate actions to control or mitigate risks. Longer-term strategies to address equipment and process design should be developed. Facilities undergoing construction or refurbishment will need to consider and adopt appropriate equipment.

New or amended requirement	Remarks
2.3 A Contamination Control Strategy (CCS) should be implemented across the facility in order to define all critical control points and assess the effectiveness of all the controls (design, procedural, technical and organisational) and monitoring measures employed to manage risks to medicinal product quality and safety. The combined strategy of the CCS should establish robust assurance of contamination prevention. The CCS should be actively reviewed and, where appropriate, updated and should drive continual improvement of the manufacturing and control methods. Its effectiveness should form part of the periodic management review. Where existing control systems are in place and are appropriately managed, these may not require replacement but should be referenced in the CCS and the associated interactions between systems should be understood.	The introduction of a CCS is a new concept in Annex 1; however, it is reflective of existing expectations for control strategies as specified in Clause 1.4, Annexes 2A. 2B, 15 and 17. The inclusion of a contamination control strategy in Annex 1 aligns with ICH Q10 requirements: *"ICH Q10 Control Strategy: A planned set of controls, derived from current product and process understanding, that assures process performance and product quality. The controls can include parameters and attributes related to drug substance and drug product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications, and the associated methods and frequency of monitoring and control."* This new clause requires manufacturers to develop and maintain a CCS document(s) and perform periodic review of the effectiveness of the CCS. While this requirement is new, existing GMP expectations require manufacturers to maintain appropriate process knowledge, (Ch1.1.4ii), and establish and maintain a state of control, (Ch1.4viii). Current expectations require the development of quality risk assessments that assess sterile good manufacturing processes (in accordance with ICHQ9), document risks and mitigating controls, and demonstrate continued effectiveness. Hence, those manufacturers that are compliant with existing expectations are highly likely to have documents for the assessment of all aspects of the CCS, (albeit these may not be termed as CCS) and may only require collation of existing documents and development of an overarching policy document. Whereas manufacturers that are not compliant with existing expectations may need to fully develop a CCS to meet Annex 1 requirements. This new requirement may result in some manufacturers needing to collate existing CCS documents and risk assessments. For those manufacturers that have not holistically assessed existing manufacturing processes, the development and collation of new CCS documents would be required.
2.5 The development of the CCS requires detailed technical and process knowledge. Potential sources of contamination are attributable to microbial and cellular debris (e.g. pyrogen, endotoxin) as well as particulate (e.g. glass and other visible and sub-visible particles).	This new clause and sub-sections provide guidance in the development of an effective CCS and the elements that should be considered. Individually, none of the sub-sections are new to the GMP guide and are expected and addressed within the existing GMP guide; however, their collation into a CCS

New or amended requirement	Remarks
Elements to be considered within a CCS should include (but are not limited to): i. design of both the plant and processes including the associated documentation ii. premises and equipment; iii. personnel; iv. utilities; v. raw material controls – including in-process controls; vi. product containers and closures; vii. vendor approval – such as key component suppliers, sterilisation of components and single use systems (SUS), and critical service providers; viii. management of outsourced activities and availability/transfer of critical information between parties, e.g. contract sterilisation services; ix. process risk management; x. process validation; xi. validation of sterilisation processes; xii. preventative maintenance – maintaining equipment, utilities and premises (planned and unplanned maintenance) to a standard that will ensure there is no additional risk of contamination; xiii. cleaning and disinfection; i. monitoring systems - including an assessment of the feasibility of the introduction of scientifically sound, alternative methods that optimize the detection of environmental contamination; ii. prevention mechanisms – trend analysis, detailed	document or system is a new requirement. Refer to item 2.3 for an assessment of the impact. Industry guidance for the development of CCS is voluminous and has existed for a number of years, therefore ample guidance as to what should be considered is readily available to facilitate adoption, e.g. ISPE, PDA, ECA etc.

New or amended requirement	Remarks
investigation, root cause determination, corrective and preventive actions (CAPA) and the need for comprehensive investigational tools; iii. continuous improvement based on information derived from the above.	
4.12 Airlocks should be designed and used to provide physical separation and to minimize microbial and particle contamination of the different areas and should be present for material and personnel moving between different grades. Wherever possible, airlocks used for personnel movement should be separated from those used for material movement. Where this is not practical, time-based separation of movement (personnel/material) by procedure should be considered. Airlocks should be flushed effectively with filtered air to ensure that the grade of the cleanroom is maintained. The final stage of the airlock should, in the "at rest" state, be of the same cleanliness grade (viable and total particle) as the cleanroom into which it leads. The use of separate change rooms for entering and leaving the grade B area is desirable. Where this is not practical, time-based separation of activities (ingress/egress) by procedure should be considered. Where the CCS indicates that the risk of contamination is high, separate change rooms for entering and leaving production areas should be used. Airlocks should be designed as follows: i. Personnel airlocks: Areas of increasing cleanliness used for entry of personnel (e.g. from the grade D area to the grade C area to the grade B area). In general hand washing facilities should be provided only in the first stage of the changing room and not be present in changing rooms directly accessing the grade B area. ii. Material airlocks: used for materials and equipment transfer. • Only materials and equipment that have been included on an approved list and assessed during validation of the transfer process, should be transferred into the grade A or grade B areas via an airlock or pass-through hatches. Equipment and materials (intended for use in the grade A area) should be protected when transiting through the grade B area. Any unapproved items that require transfer should be pre-approved as an exception. Appropriate risk assessment and mitigation measures should be applied and recorded as per the manufacturer's CCS and should include a specific disinfection and monitoring programme approved by quality assurance.	This is a modified clause; however, is identical in intent to existing Annex1§51 & 81 in PE009-16. Modification and/or additional text included to add clarity or guidance for manufactures to aid achieving compliance. Additional operational controls for ingress and egress of staffs, i.e. a unidirectional process, or time-based separation to avoid cross-contamination. Text referencing the CCS included, to provide clarity that the CCS should determine the level of controls required for personnel access into cleanrooms. Text relating to the control of materials that are transferred into cleanrooms, ensuring that only approved materials are transferred Differentiation between Airlock and pass-through, noting that pass-through is a subset of the former, is not used for personnel access or transfer, and is typically smaller in size than an airlock. However, the principles of operation and maintenance of cleanliness are identical. The changes reflect existing TGA and GMP expectations and do not invoke additional requirements. Some manufacturers may need to develop lists (from validation) to control materials introduced into the cleanrooms. The information for these lists should be readily available from the decontamination validation studies already in use.

<table>
<tr><th>New or amended requirement</th><th>Remarks</th></tr>
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• Pass-through hatches should be designed to protect the higher-grade environment, for example by effective flushing with an active filtered air supply.

• The movement of material or equipment from lower grade or unclassified area to higher grade clean areas should be subject to cleaning and disinfection commensurate with the risk and in line with the CCS.
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<tr><td>
4.31 The microbial contamination level of the cleanrooms should be determined as part of the cleanroom qualification. The number of sampling locations should be based on a documented risk assessment and the results obtained from room classification, air visualization studies and knowledge of the process and operations to be performed in the area. The maximum limits for microbial contamination during qualification for each grade are given in Table 2. Qualification should include both “at rest” and “in operation” states.

<table>
<tr><th>Table 2: Maximum permitted microbial contamination level during qualification Grade</th><th>Air sample CFU/m3</th><th>Settle plates (diameter 90 mm) CFU/4 hours (a)</th><th>Contact plates (diameter 55 mm) CFU/plate</th></tr>
<tr><td>A</td><td colspan="3">No growth</td></tr>
<tr><td>B</td><td>10</td><td>5</td><td>5</td></tr>
<tr><td>C</td><td>100</td><td>50</td><td>25</td></tr>
<tr><td>D</td><td>200</td><td>100</td><td>50</td></tr>
</table>
a) Settle plates should be exposed for the duration of operations and changed as required after a maximum of 4 hours. Exposure time should be based on recovery studies and should not allow desiccation of the media used.

Note 1: All methods indicated for a specific grade in the table should be used for qualifying the area of that specific grade. If one of the methods tabulated is not used, or alternative methods are used, the approach taken should be appropriately justified.

Note 2: Limits are applied using CFU throughout the document. If different or new technologies are used that present results in a manner different from CFU, the manufacturer should scientifically justify the limits applied and where possible correlate them to CFU.

Note 3: For the qualification of personnel gowning, the limits given for contact plates and glove prints in Table 6 should apply.
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This is a new clause, however, it is similar in intent to existing Annex1§19 in PE009-16. Modification and/or additional text included to add clarity or guidance for manufactures to aid achieving compliance.
- Reflect existing expectation (and industry practice) that microbiological qualification of clean areas is essential to assure the correct cleanliness of the clean areas, before use and routinely during reclassification and remediation.
- Grade A limits have been amended from <1cfu to ‘no growth’ to clarify that the recovery of any isolates from these grades requires investigation/remedial action.
- Removal of ‘averaging’ of recoveries, as this led to ambiguity as to what the correct (appropriate) practice was. TGA’s position since 2012 was not to allow averaging.
- Clarification that all sampling methods listed should be used, unless scientifically justified. This inclusion aligns with existing GMP and TGA expectations of the PIC/S PI 032-2 section 4.
- Guidance for the use of rapid/alternative methods, noting this guidance does not mandate the use of these methods.
- Clarification that surface limits apply to gowns and gloves, consistent with current TGA expectations.

The changes reflect existing TGA and GMP expectations and do not invoke additional requirements, other than minor procedural changes, e.g. changes to internal procedures for classification.
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</table>

New or amended requirement	Remarks
Note 4: Sampling methods should not pose a risk of contamination to the manufacturing operations.	
7.14 Cleanroom gowning should be performed in change rooms of an appropriate cleanliness grade to ensure gown cleanliness is maintained. Outdoor clothing including socks (other than personal underwear) should not be brought into changing rooms leading directly to grade B and C areas. Single or two-piece facility trouser suits, covering the full length of the arms and the legs, and facility socks covering the feet, should be worn before entry to change rooms for grades B and C. Facility suits and socks should not present a risk of contamination to the gowning area or processes.	This is a modified clause; however, similar in intent to existing Annex1§44, 45 & 51 expectations regarding gown management in PE009-16. Modification and/or additional text included to add clarity or guidance for manufactures to aid achieving compliance. - Clarity that gowning should occur in a space that protects the gowns from contamination. - Additional controls regarding socks worn in higher grade areas, as a contamination control measure. - Clarification on the use of facility gowns that are worn underneath outer gowns in grade C/B/A areas, to protect the outer gown from contamination during gowning. Most of these changes reflect existing TGA and GMP expectations and do not invoke additional requirements. The addition of facility socks is a new requirement invoked by Annex 1 amendments and is necessitated by the significant contamination risk presented by personnel wearing outdoor socks during critical gowning operations and the entrainment of contaminants into production areas. The principle behind this requirement is not new; however, due to the prescriptive nature of this control it is recognised that some site will have to modify practices to utilise appropriate socks. Socks are not required to be sterile, and TGA's basic expectation is that they are managed in the same manner that facility suits are managed, e.g. only worn within the facility, and changed and laundered at a frequency based on risk. It is acknowledged that there may be additional cost of socks and their processing for a minority of domestic manufacturers who do not already utilise cleanroom socks. There are no anticipated actions required for the majority of aseptic sites that currently utilise facility socks.
7.18 Activities in clean areas that are not critical to the production processes should be kept to a minimum, especially when aseptic operations are in progress. Movement of personnel should be slow, controlled and methodical to avoid	Modified clause, however, identical in intent to existing Annex1§73 expectations in PE009-16.

New or amended requirement	Remarks
excessive shedding of particles and organisms due to over-vigorous activity. Operators performing aseptic operations should adhere to aseptic technique at all times to prevent changes in air currents that may introduce air of lower quality into the critical zone. Movement adjacent to the critical zone should be restricted and the obstruction of the path of the unidirectional (first air) airflow should be avoided. A review of airflow visualisation studies should be considered as part of the training programme.	Modification and/or additional text included to add clarity or guidance for manufactures to aid achieving compliance. - Minimising any activities in aseptic areas that are not essential to operations. - Additional text to support appropriate aseptic practices. - Use of airflow visualisation studies to reinforce good practices and aid operator training. These changes generally reflect existing TGA and GMP expectations and do not invoke significant additional requirements. Some modification to training methodologies may be required to ensure that air-flow visualisation is incorporated as a training tool.
8.19 Aseptic operations (including APS) should be observed on a regular basis by personnel with specific expertise in aseptic processing to verify the correct performance of operations including operator behaviour in the cleanroom and address inappropriate practices if detected.	New clause, however, identical in intent to clause 2.7 & 2.9 expectations in PE009-16. Modification and/or additional text included to add clarity or guidance for manufactures to aid achieving compliance. - Clarity of Requirement for independent observation of routine operations and media fills to ensure operations are conducted appropriately. This is standard practice for most manufacturers. - Similar in intent to existing guidance within PIC/S PI-007" Validation of Aseptic Processes" clause 5.1.8, that encourages the recording of aseptic process simulations, in order to determine that appropriate practices were observed and assist with investigation where warranted. Some manufacturers may need to adjust existing procedures /records if they do not currently review operations or APS.
9.31 Microorganisms detected in the grade A and grade B areas should be identified to species level and the potential impact of such microorganisms on product quality (for each batch implicated) and overall state of control should be evaluated. Consideration should also be given to the identification of microorganisms detected in grade C and D areas (for example where action limits or alert levels are exceeded) or following the isolation of organisms that may indicate a loss of control, deterioration in cleanliness or that may be difficult to control such as spore-forming microorganisms and moulds and at a sufficient frequency to maintain a current understanding of the typical flora of these areas.	This is a new clause, however, similar in intent to Annex 1§20 in PE009-16. Modification and/or additional text included to add clarity or guidance for manufactures to aid achieving compliance. - Guidance to assist in development of a compliant identification policy. - Reflects (in part) PE0031-2 guidance section 4.3, with additional scope to grade B, and potentially C and D if warranted, based on risk, e.g. monitoring or identification of organisms that are objectionable, atypical or indicative of control failure. These changes generally reflect existing TGA and GMP expectations.

New or amended requirement	Remarks
	Manufacturing sites that do not currently speciate isolates from Grade B may need to introduce additional testing and identification of isolates from these grades.
9.42 Where processes include materials that contact the product contact surfaces but are then discarded (e.g. product flushes), the discarded material should be simulated with nutrient media and be incubated as part of the APS, unless it can be clearly demonstrated that this waste process would not impact the sterility of the product.	This is a new clause, with no direct equivalent in PE009-16. Modification and/or additional text included to add clarity or guidance for manufactures to aid achieving compliance. - Guidance to reflect PI007-6 PIC/S Recommendation on the validation of aseptic processes. - Guidance for the incubation of solutions used to mimic aseptic flushing of processes, e.g. filter preparation or otherwise. These changes reflect existing TGA and GMP expectations, and thus most manufacturers would already be compliant with this clause. Manufacturers may need to make minor updates to APS procedures, where relevant to their process design.
9.46 The target should be zero growth. Any contaminated unit should result in a failed APS and the following actions should be taken: i. an investigation to determine the most probable root cause(s); ii. determination and implementation of appropriate corrective measures; iii. a sufficient number of successful, consecutive repeat APS (normally a minimum of 3) should be conducted in order to demonstrate that the process has been returned to a state of control; iv. a prompt review of all appropriate records relating to aseptic production since the last successful APS; a) The outcome of the review should include a risk assessment of potential sterile breaches in batches manufactured since the last successful APS. b) All other batches not released to the market should be included in the scope of the investigation. Any decision regarding their release status should consider the investigation outcome. v. all products that have been manufactured on a line subsequent to a process simulation failure should be quarantined until a successful resolution of the process simulation failure has occurred;	Modified clause, however, similar in intent to Clause 69 & 70 in PE009-16. Modification and/or additional text included to add clarity or guidance for manufactures to aid achieving compliance. - More stringent acceptance criteria, noting that process design and capability should readily achieve a zero growth APS, and that any contamination warrants a full investigation, noting the risk to product quality and patient safety. - Guidance for the investigation of APS failure. - Clarity that revalidation (3 runs) would be expected following failure and remediation. - Guidance to reflect PI007 These changes reflect existing TGA and GMP expectations, and thus most manufacturers would already be compliant with this clause. Some manufacturers may need to make minor updates to some procedures and protocols for APS.

New or amended requirement	Remarks
vi. where the root cause investigation indicates that the failure was related to operator activity, actions to limit the operator's activities, until retrained and requalified, should be taken; vii. production should resume only after completion of successful revalidation.	
9.48 An APS run should be aborted only under circumstances in which written procedures require commercial lots to be equally handled. An investigation should be documented in such cases.	This is a new clause, with no direct equivalent in PE009-16. Modification and/or additional text included to add clarity or guidance for manufactures to aid achieving compliance. - Clause to prevent cancellation of APS without appropriate justification. These changes reflect existing TGA and GMP expectations. Some manufacturers may need to make minor updates to some procedures and protocols for APS.

Transition plan

The transition period from 1 September 2025 to 1 March 2026 serves to allow manufacturers to assess and plan for these changes and permit time for implementation.

For the most significant changes, we have produced transition plan tables, which summarise the minimum requirements to demonstrate compliance

The approach that will be taken where these have not been met is outlined below.

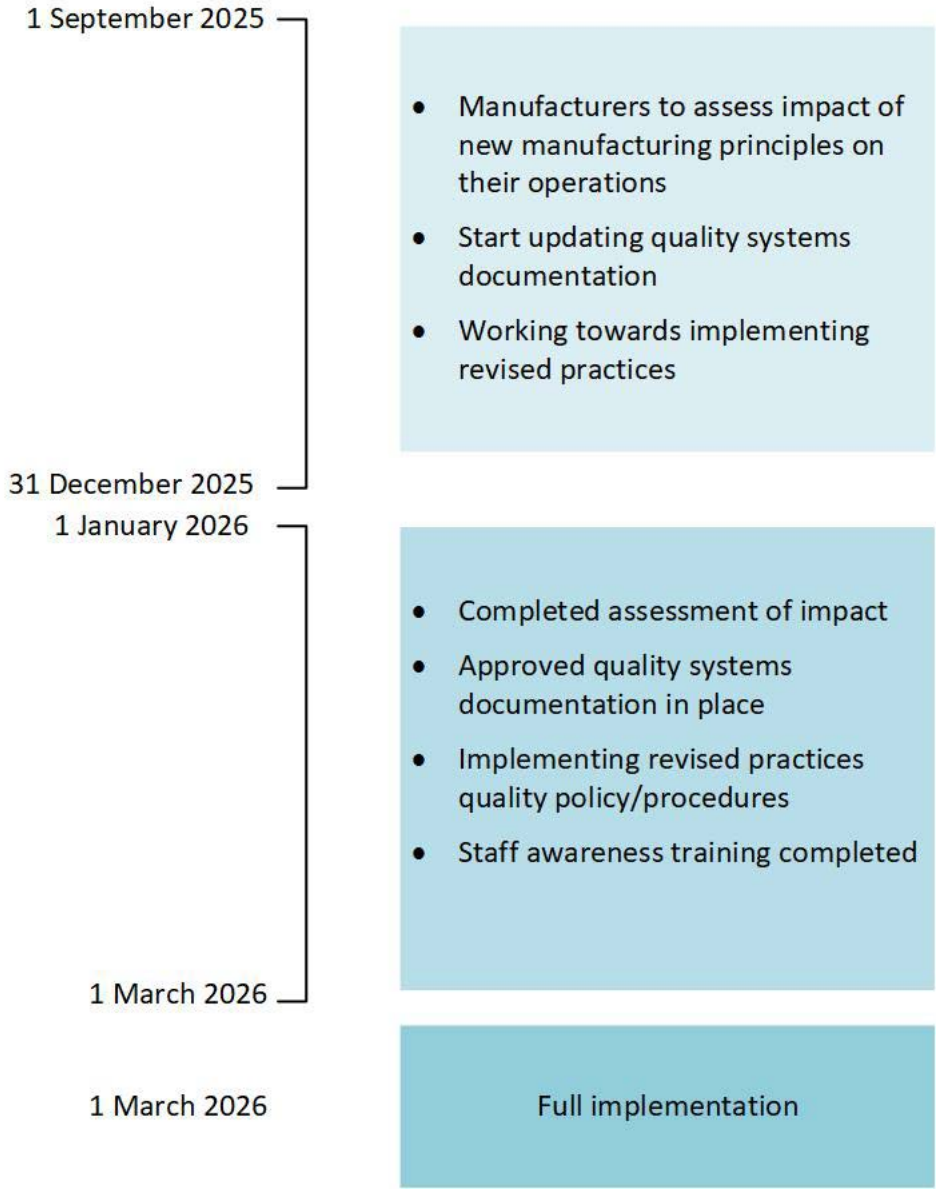
Compliance with all other changes is expected from 1 September 2025 and transition arrangements do not apply.

Our expectation is that by 1 January 2026, manufacturers will have:

- completed their assessment of the impact of the new manufacturing principles on their operations
- completed, or be well advanced, towards updating quality systems documentation and implementing revised practices

We recognise the complexity associated with these changes and have therefore provided appropriate timeframes for implementation, which reflect the complexity and significance of each change. Where the impact is minimal to the manufacturer, we would expect that adoption would be well progressed or implemented by 1 January 2026, unless justified.

Transition plan diagram



Reporting deficiencies in Post Inspection Letters (PIL)

We issue a PIL at the conclusion of an on-site inspection to communicate departures from GMP, with the purpose of assisting companies to restore compliance through root cause assessment and corrective actions.

During the transitional implementation period, we will be aiming to assist and encourage implementation of the new requirements. As a result, we will not cite a deficiency when companies demonstrate they are meeting the minimum expectations summarised below.

We will report a deficiency if the company has not undertaken an appropriate approach to implementing the new requirements or may not achieve compliance in a timely manner. This will usually be cited as an ‘other’ deficiency against the relevant part of the PIC/S Guide to GMP.

Major deficiencies will generally be cited only where a manufacturer has not commenced, or significantly progressed, action to implement the new PIC/S Guide to GMP requirements. A major deficiency may also be cited where a manufacturer’s implemented procedures and systems do not meet the requirements of the PIC/S Guide to GMP.

Transition plan tables

PIC/S GMP Requirement	Between 1 September 2025 and 1 January 2026	Between 1 January 2026 and 1 March 2026	From 1 March 2026
Clause 2.1 Principle	• Review updated clause • Evaluate impact to existing facility/process design and identify any inappropriately designed processes/equipment. • Review process/equipment risk assessments for identified processes • Identify intermediate risk-mitigating actions and controls, and review and implement appropriate (augmented) monitoring activities.	• Implement intermediate risk-mitigation activities, controls and appropriate monitoring. • Develop long-term strategies to address process or equipment design limitations.	Full implementation.

PIC/S GMP Requirement	Between 1 September 2025 and 1 January 2026	Between 1 January 2026 and 1 March 2026	From 1 March 2026
Clause 2.3 – 2.5 Contamination Control Strategy	• Review updated clause and identify CCS requirements embedded across Annex 1 • Evaluate existing contamination control documents and system within the PQS for compliance with updated Annex 1 requirements. • Document any compliance gaps identified and planned actions for remediation.	• Commence drafting procedures to link existing contamination control documents, and address gaps identified. • Develop and implement system for periodic review of CCS and monitoring for effectiveness. • Commence training staff in updated procedures	Full implementation.

PIC/S GMP Requirement	Between 1 September 2025 and 1 January 2026	Between 1 January 2026 and 1 March 2026	From 1 March 2026
Clause 4.12 Control of materials transferred into cleanrooms	• Review updated clause • Identify materials and equipment authorised and validated for transfer into cleanrooms. • Create and implement lists of authorised materials that may be transferred into the grade A or grade B areas via an airlock or pass-through hatches	Full implementation.	Full implementation.

PIC/S GMP Requirement	Between 1 September 2025 and 1 January 2026	Between 1 January 2026 and 1 March 2026	From 1 March 2026
Clause 4.31 Microbiological qualification of cleanrooms	• Review updated clause • Identify qualification and monitoring procedures impacted by the change to microbial limits for Grade A environments. • Update and authorise procedures within the PQS.	Full implementation.	Full implementation.

PIC/S GMP Requirement	Between 1 September 2025 and 1 January 2026	Between 1 January 2026 and 1 March 2026	From 1 March 2026
Clause 7.14 Cleanroom gowning - socks	• Review updated clause • Identify facility procedures and gowning practices that require the addition of facility socks. • Identify any required validation or qualification activities. • Commence supplier identification and qualification for suppliers of facility socks.	• Complete supplier qualification and obtain facility socks. • Conduct any necessary revalidation or qualification activities. • Implement updated gowning procedures and use of facility socks	Full implementation.

PIC/S GMP Requirement	Between 1 September 2025 and 1 January 2026	Between 1 January 2026 and 1 March 2026	From 1 March 2026
Clause 7.18 Airflow visualisation training	• Review updated clause • Identify existing critical air-flow visualisation studies. • Modify existing cleanroom training materials to incorporate air-flow visualisation information.	• Commence training staff in updated procedures	Full implementation.

PIC/S GMP Requirement	Between 1 September 2025 and 1 January 2026	Between 1 January 2026 and 1 March 2026	From 1 March 2026
Clause 8.19 Observation of APS	• Review updated clause • Commence modification of APS procedures to include observation of APS by personnel with specific expertise in aseptic processing.	• Commence training staff in updated procedures • Implement updated APS procedures and conduct observation, recording and utilisation of observation feedback.	Full implementation.

PIC/S GMP Requirement	Between 1 September 2025 and 1 January 2026	Between 1 January 2026 and 1 March 2026	From 1 March 2026
Clause 9.31 Microbial identification policy	• Review updated clause • Commence update and review of microbial identification policy to include identification of grade B isolates and required response(s) to identification of organisms that may indicate a loss of control, deterioration in cleanliness or that may be difficult to control.	• Commence training staff in updated procedures. • Introduce identification to species level of isolates from Grade B and remedial actions.	Full implementation.

PIC/S GMP Requirement	Between 1 September 2025 and 1 January 2026	Between 1 January 2026 and 1 March 2026	From 1 March 2026
Clause 9.42 APS protocol design	• Review updated clause • Identify relevance of new clause to current operations. • Commence drafting of modified procedures as required.	• Commence training staff in updated procedures. • Incorporate updated APS design in APS program.	Full implementation.

PIC/S GMP Requirement	Between 1 September 2025 and 1 January 2026	Between 1 January 2026 and 1 March 2026	From 1 March 2026
Clause 9.46 APS acceptance criteria	• Review updated clause • Identify relevance of new clause to current operations. • Commence drafting of modified procedures as required, with updates to acceptance criteria.	• Commence training staff in updated procedures. • Incorporate updated APS acceptance criteria to APS program.	Full implementation.

PIC/S GMP Requirement	Between 1 September 2025 and 1 January 2026	Between 1 January 2026 and 1 March 2026	From 1 March 2026
Clause 9.48 Criteria for abortion of APS	• Review updated clause • Identify relevance of new clause to current operations. • Commence drafting of modified procedures as required, with details of the circumstances under which an APS may be aborted.	• Commence training staff in updated procedures	Full implementation.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Manufacturing Quality Branch	August 2025

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Reference/Publication #