# Common Deficiencies Identified at Inspection

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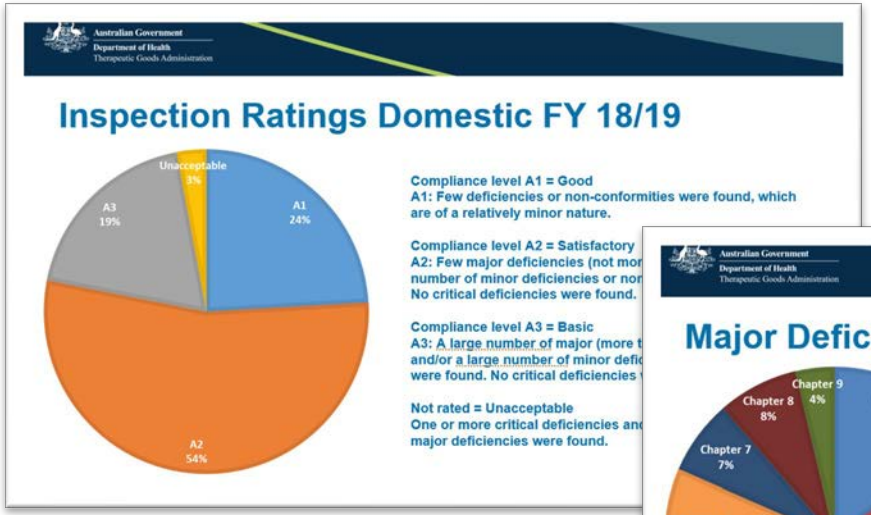
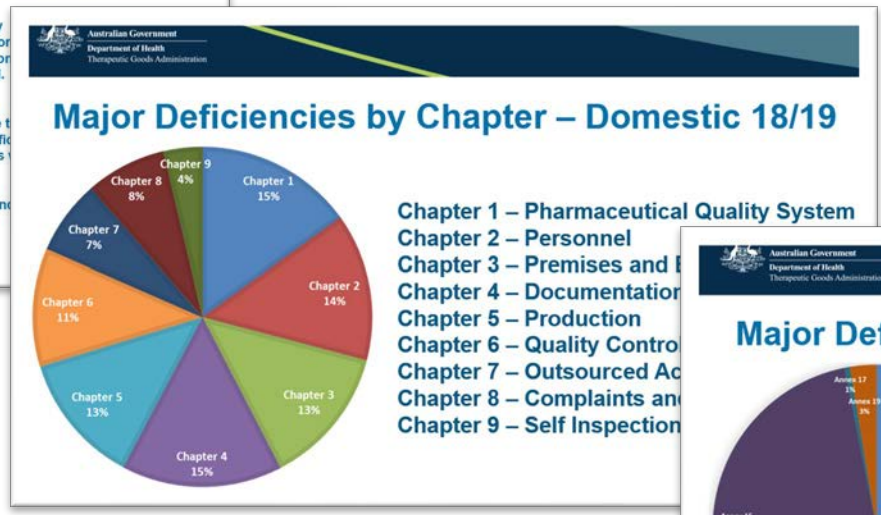
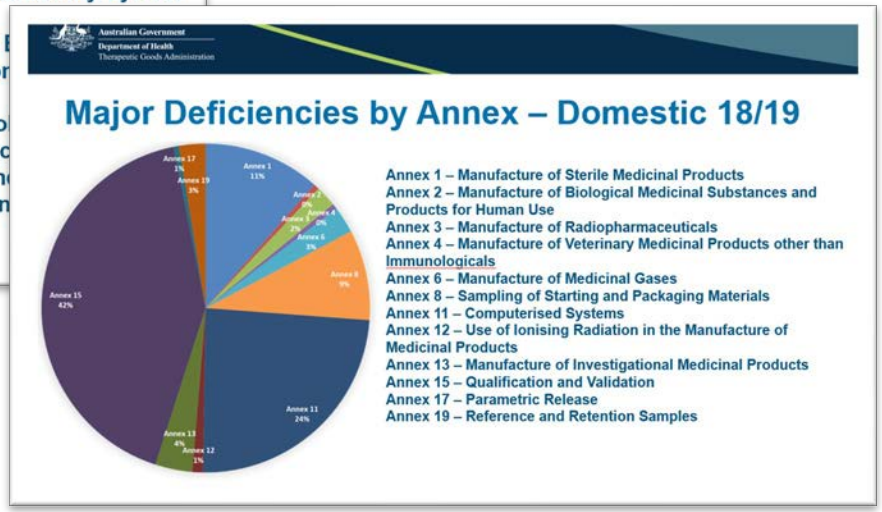
GMP FORUM 2024

# Common Deficiencies 2019 and 2024

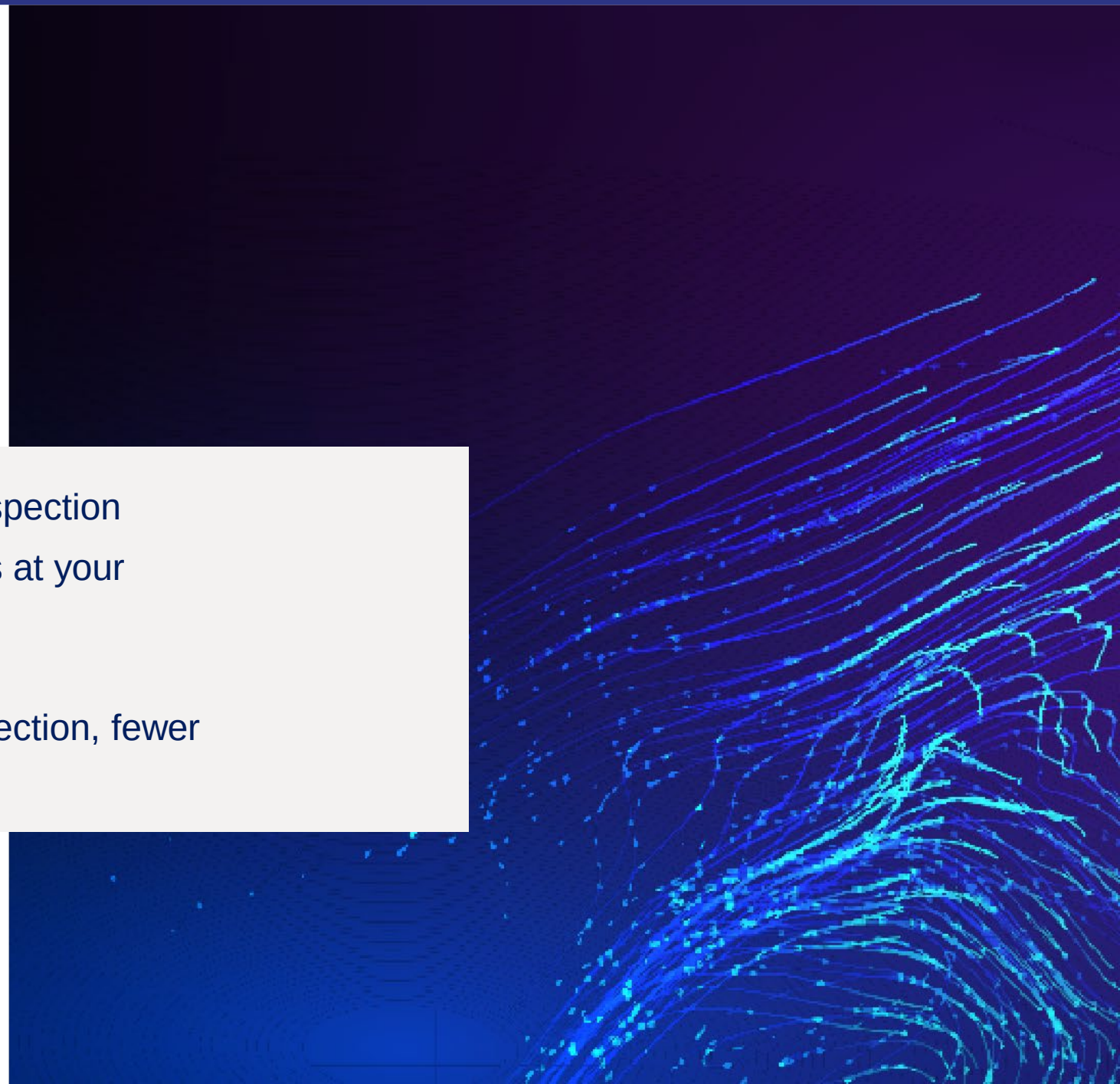


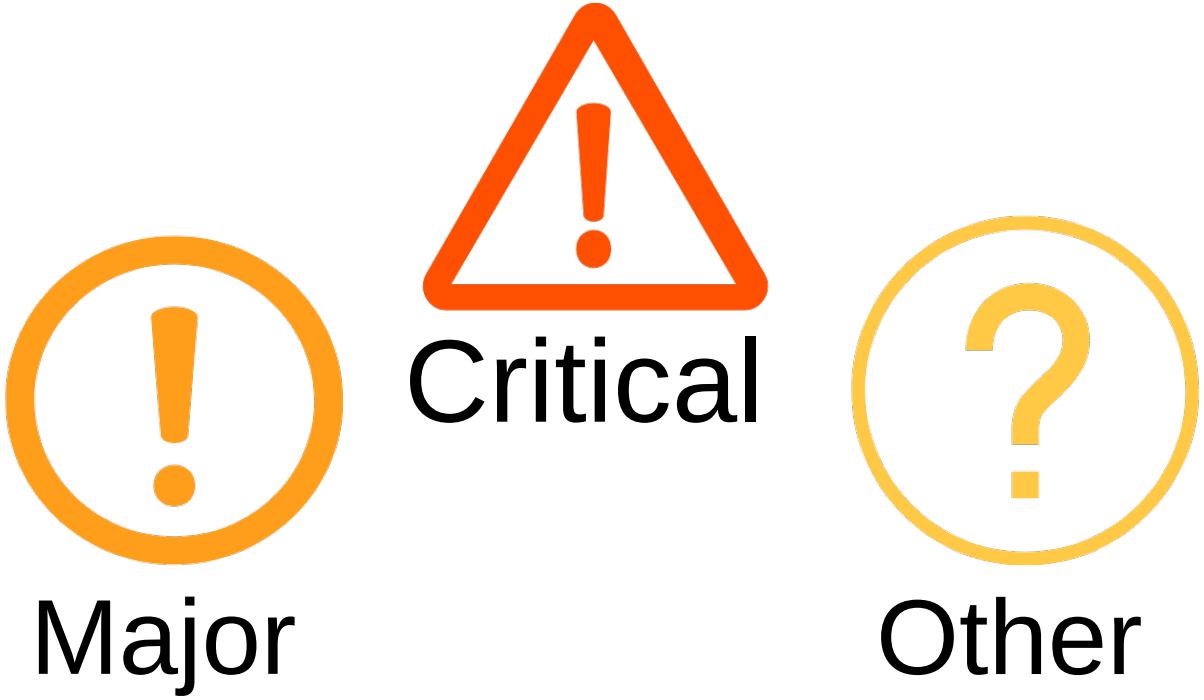
# Agenda

- Manufacturers – fewer deficiencies at inspection
- Sponsors – telltale signs of bigger issues at your inspections
- Consumers – better products
- Auditors – fewer issues identified at inspection, fewer things to write up and report



# Defining Deficiencies

Deficiency = non-compliance
1 of 3 types of deficiencies



Critical

Major

Other

# Deficiency Classification

## Critical Definition

- A 'critical deficiency' is a serious situation that requires immediate resolution and will result in regulatory action being considered, including suspension or cancellation of your GMP licence or GMP clearance. A deficiency can be critical when one of the following is observed:
- a practice or process has produced, or may result in, a significant risk of producing a product that is harmful to the user
- the manufacturer has engaged in fraud, misrepresentation or falsification of products or data

**Sample Critical Deficiency**

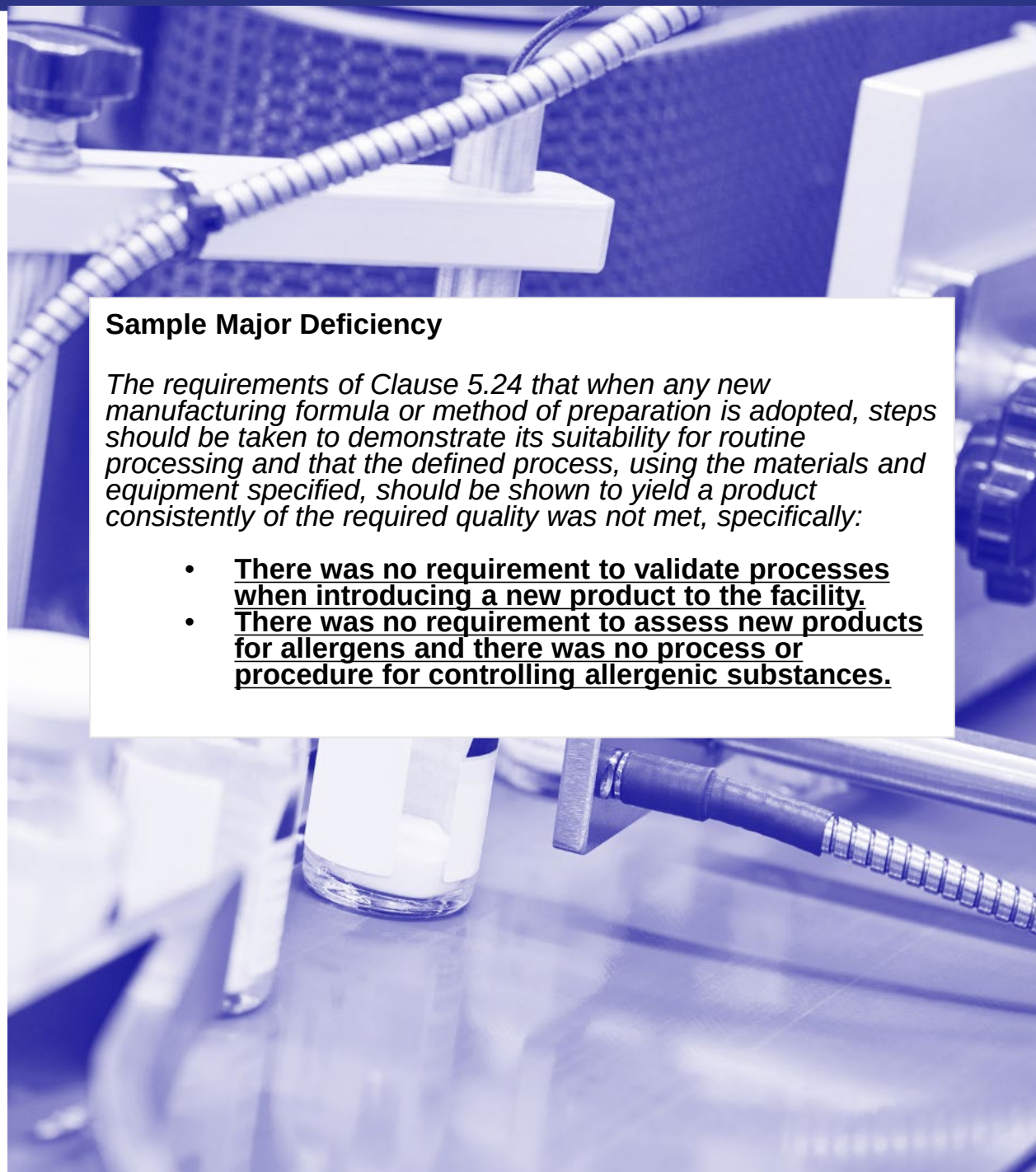
*The requirements of the Principle of Chapter 3 and Clause 3.6 that premises and equipment must be located, designed, constructed, adapted and maintained to suit the operations to be carried out, that their layout and design must aim to minimise the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build-up of dust or dirt and, in general, any adverse effect on the quality of products, and that cross-contamination should be prevented for all products by appropriate design and operation of manufacturing facilities, that the measures to prevent cross-contamination should be commensurate with the risks, that Quality Risk Management principles should be used to assess and control the risks and that depending of the level of risk, it may be necessary to dedicate premises and equipment for manufacturing and/or packaging operations to control the risk presented by some medicinal products was not met specifically:*

- **The filling lines were located within a warehouse facility that was not sealed to the external environment and contained windows, roller doors and exhaust fans to the external environment.**
- **There was no physical separation, such as walls or barriers, to segregate between the seven manufacturing lines that were located within 3-meters of each other.**

# Deficiency Classification

## Major Definition

- A 'major deficiency' is a non-critical deficiency for which one or more of the following apply:
- has produced or may produce a product which does not comply with its marketing authorisation (in some circumstances this could be critical)
- indicates a major deviation from the Code of GMP
- indicates a major deviation from the terms of the manufacturing licence, or GMP approval (overseas manufacturers)
- indicates a failure to carry out satisfactory procedures for release of batches
- indicates a failure of the person responsible for QA/QC to fulfil his/her duties
- consists of several other deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such



**Sample Major Deficiency**

*The requirements of Clause 5.24 that when any new manufacturing formula or method of preparation is adopted, steps should be taken to demonstrate its suitability for routine processing and that the defined process, using the materials and equipment specified, should be shown to yield a product consistently of the required quality was not met, specifically:*

- **There was no requirement to validate processes when introducing a new product to the facility.**
- **There was no requirement to assess new products for allergens and there was no process or procedure for controlling allergenic substances.**

# Deficiency Classification

## Other Definition

- An 'other deficiency' is a deficiency that cannot be classified as either critical or major, but indicates a departure from GMP.

- Deficiencies may be classified as 'other' when there is insufficient evidence to classify as major or critical. Note that these deficiencies are not considered minor, and it is important that the manufacturer appropriately investigates these issues to determine the true extent of the deficiency.

**Sample Other Deficiency**

*The requirements of Clause 3.25 regarding printed packaging materials, that special attention should be paid to the safe and secure storage of these materials was not met, for example:*

- **a product label belonging to batch XYZ was found in the stability storeroom, it was explained to the inspector that this was not supposed to be in that room, and that there were no records for this label.**

# PIC/S Guide to GMP by Chapters (Part 1 only)

Chapter 1 – Pharmaceutical Quality System
Chapter 2 – Personnel
Chapter 3 – Premises and Equipment
Chapter 4 – Documentation
Chapter 5 – Production
Chapter 6 – Quality Control
Chapter 7 – Outsourced Activities
Chapter 8 – Complaints and Product Recall
Chapter 9 – Self Inspection

## PRINCIPLE OF CHAPTER 1

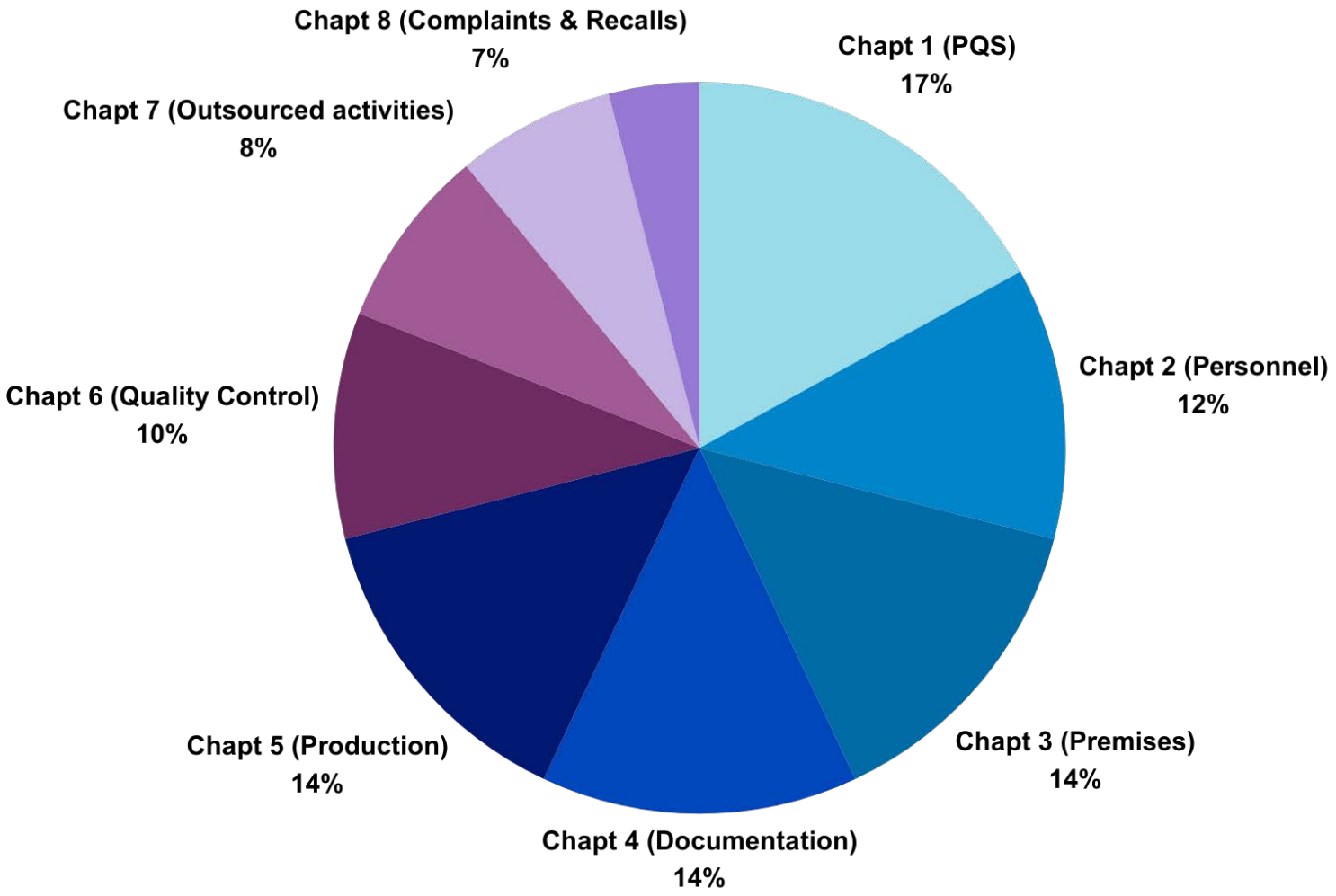
The holder of a Manufacturing Authorisation must manufacture medicinal products so **as to ensure that they are fit for their intended use**, comply with the requirements of the Marketing Authorisation or Clinical Trial Authorisation, as appropriate, **and do not place patients at risk due to inadequate safety, quality or efficacy**.

# Deficiency Format

**The requirements of [CLAUSE] that [WHAT THE CLAUSE SAYS] was not met, for example, [ISSUE IDENTIFIED]**

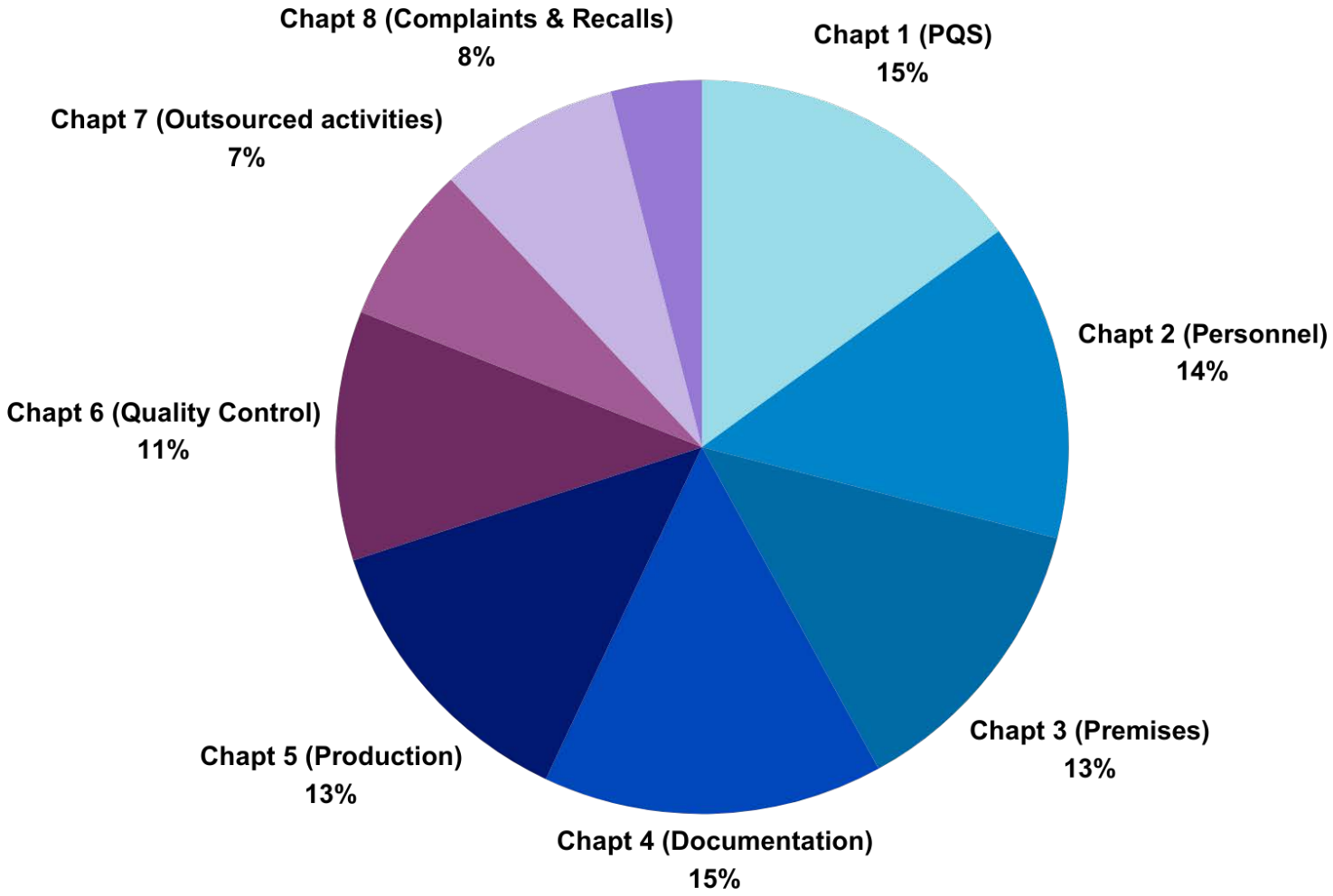
**Example**: The requirements of ***[Clause 5.1]*** that ***[production should be performed and supervised by competent people]*** was not met as evidenced by, personnel performing the steps in manufacturing did not have training records for the tasks that they were observed to be performing at the time of the inspection, for example, operators X, Y and Z.

# 2024 Deficiencies by Chapter




Chapter 1 – Pharmaceutical Quality System
Chapter 2 – Personnel
Chapter 3 – Premises and Equipment
Chapter 4 – Documentation
Chapter 5 – Production
Chapter 6 – Quality Control
Chapter 7 – Outsourced Activities
Chapter 8 – Complaints and Product Recall
Chapter 9 – Self Inspection

# 2019 Deficiencies by Chapter




Chapter 1 – Pharmaceutical Quality System
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Chapter 8 – Complaints and Product Recall
Chapter 9 – Self Inspection

# Inspection Ratings 2023-2024

## Compliance Ratings

Compliance level A1 = Good
A1: Few deficiencies or non-conformities were found, which are of a relatively minor nature.

Compliance level A2 = Satisfactory
A2: Few major deficiencies (not more than five) and/or a larger number of minor deficiencies or non-conformities were found. No critical deficiencies were found.

Compliance level A3 = Basic
A3: A large number of major (more than five, not more than 10) and/or a large number of minor deficiencies/non-conformities were found. No critical deficiencies were found.

Not rated = Unacceptable
One or more critical deficiencies and/or a large number of major deficiencies were found.

**<u>This means:</u>**

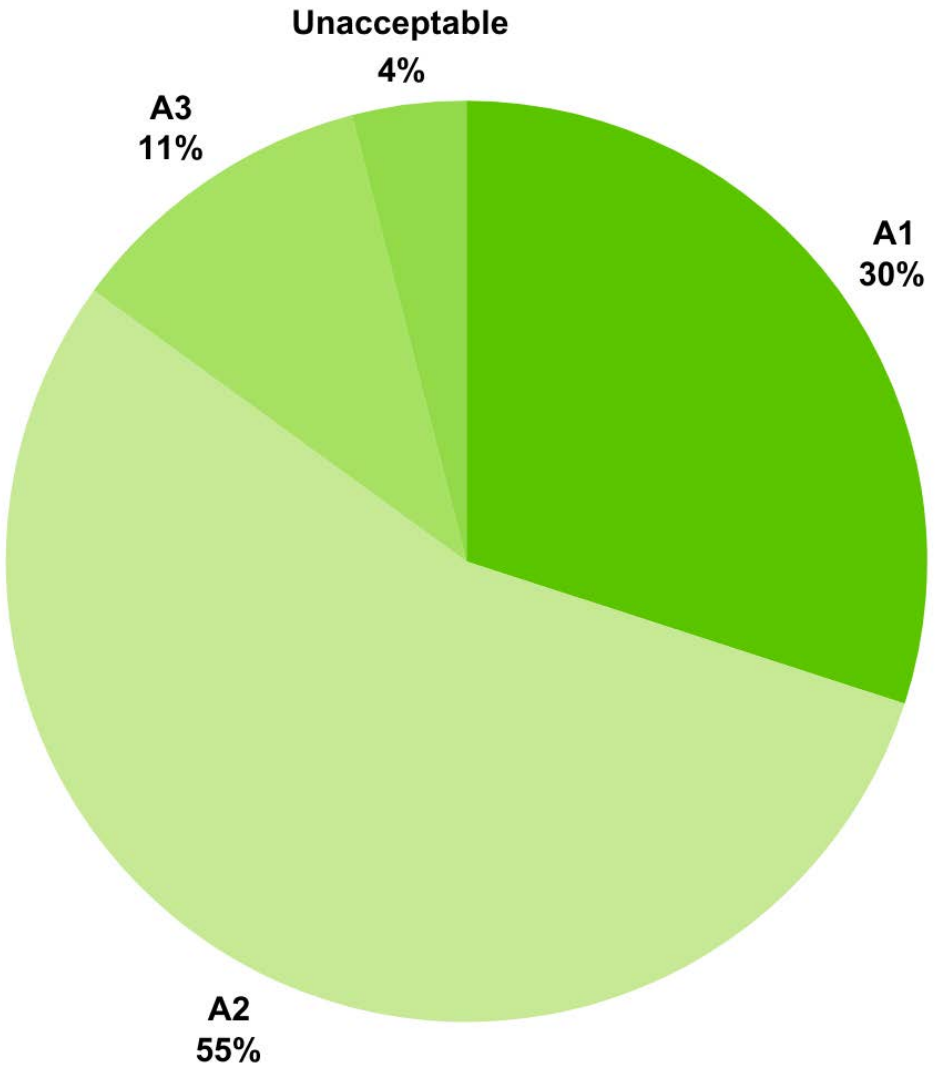
**A1 = GOOD**
No Critical, No Major, fewer than 10 Others

**A2 = Satisfactory**
No Critical, fewer than 6 Major, not many Others

**A3 = Basic**
No Critical, 6-10 Major, not many Others

**Not Rated or Unacceptable**
One or more Critical, 11 or more Major, not many Others

# Inspection Compliance Ratings 2023-2024



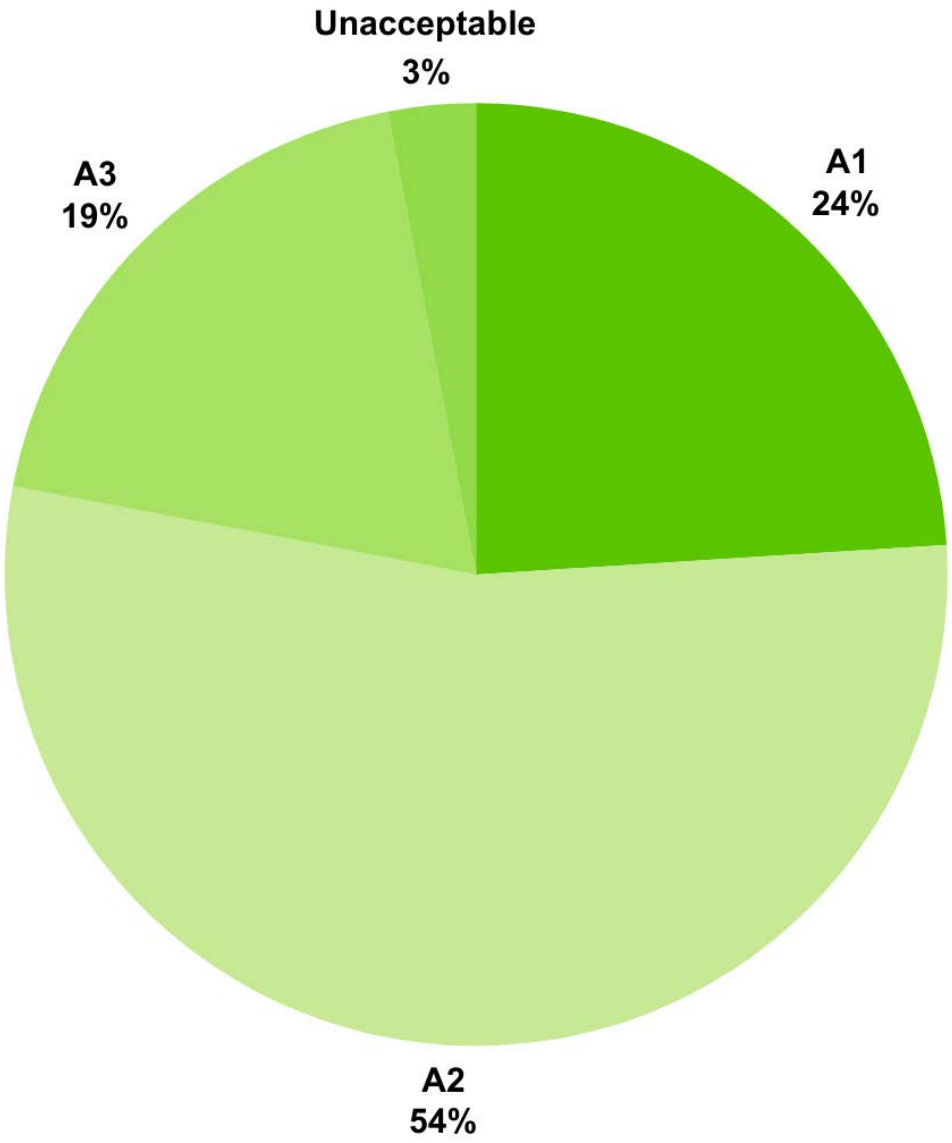

Compliance level A1 = Good 30%

Compliance level A2 = Satisfactory 55%

Compliance level A3 = Basic 11%

Not rated or Unacceptable 4%

# Inspection Compliance Ratings 2019




Compliance level A1 = Good 24%

Compliance level A2 = Satisfactory 54%

Compliance level A3 = Basic 19%

Not rated or Unacceptable 3%

# Welcome to: StrugglePharm

You are going to be acting as Pharmaceutical Quality Systems consultants at StrugglePharm to help them make high level decisions that can be the difference between a good decision and critical or major deficiencies at inspection.

Remember, they're heading into an inspection, so what you help them decide is likely to be reviewed soon.

Scenario: StrugglePharm employs one person in the quality team who is responsible for the development, management, maintenance, and execution the quality system for pharmaceutical products as well as the side project of the food manufacturing facility next door. StrugglePharm manufactures and releases for supply about 100 batches a year.

There was no training for release for supply and operations tasks, it was all OTJ, however, there were no records kept of this training. Records for investigations and the rationale for conclusions made were not kept and recently, the quality manager had found that equipment and room qualifications documents had been lost.

StrugglePharm had also recently performed a recall as the labelling on a product released to market did not contain the right warnings for pregnancy, but because they were not resourced well enough to perform the recall, Ma Struggle decided to just sign the recall declaration that the recall was done properly.

In this situation, the StrugglePharm should:

a) This is fine, business as usual, it will get better with time.
b) Acknowledge that there are failing systems and look to resource the QA manager to manage the issues.
c) Continue signing declarations to the TGA for performing recalls for product when those recalls were not actually performed.
d) Continue until the regulator discovers your GMP issues and think about fixing it then.

# Resourcing

## Consider Using:

- Resource planning tools and assessments for resource allocation.
- Using Quality Management Reviews to identify and flag resourcing issues.
- Annex 20 (QRM) to identify your process risks and assist with resource allocation.

# Chapter 1 - Clause 1.5

## Resourcing

To ensure an effective Pharmaceutical Quality System is in place, adequately resourced and that roles, responsibilities, and authorities are defined, communicated and implemented throughout the organisation, that senior management's leadership and active participation in the Pharmaceutical Quality System is essential, that this leadership should ensure the support and commitment of staff at all levels.

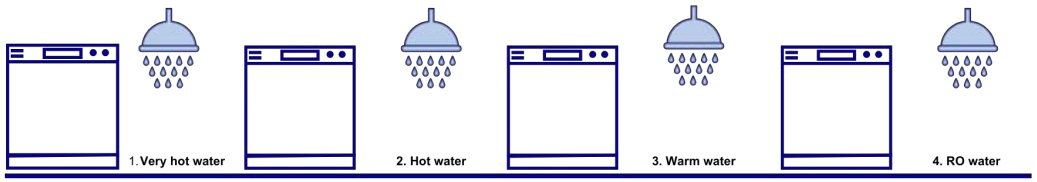
**This means:** work out what needs to be done in your quality system and allocate adequate resources to ensure the system works and is maintained.

**Common indicators for resourcing issues include:**

- Lagging PQRs
- Outdated procedures and documents
- Lagging or incomplete internal audits
- Late or incomplete training and re-training

Scenario: StrugglePharm's industrial equipment washing machine was used to wash the product moulds and trays with detergent, followed by 3 hot water rinses a final RO water rinse process.

StrugglePharm had consecutive (above limit) high counts of microbes of the final rinse water sampled from the RO outlet in the washing system:




In this situation, StrugglePharm should:

a) Perform an investigation and RCA and identify and resolve the root cause.
b) Conclude that the rest of the water in the washing system was contaminating the RO water sampling process and resolve this issue by installing a specific sampling port for RO water only.
c) Continue manufacturing without change to the process as there was a further manual IPA wipe down of the mould and trays downstream.
d) Neglect to perform a risk assessment on products manufactured with this known issue

# Investigations and RCA

## Consider:

- Identifying the organism(s) may help determine the source of the contamination
- Establishing RCA tools relevant for your organisation and the product being manufactured.
- Consider building QRM into all aspects of your PQS

# Chapter 1 - Clause 1.4 (xiv)

## Investigations and RCA

- A Pharmaceutical Quality System appropriate for the manufacture of medicinal products should ensure that: An appropriate level of root cause analysis should be applied during the investigation of deviations, suspected product defects and other problems. This can be determined using Quality Risk Management principles. In cases where the true root cause(s) of the issue cannot be determined, consideration should be given to identifying the most likely root cause(s) and to addressing those. Where human error is suspected or identified as the cause, this should be justified having taken care to ensure that process, procedural or system based errors or problems have not been overlooked, if present. Appropriate corrective actions and/or preventive actions (CAPAs) should be identified and taken in response to investigations. The effectiveness of such actions should be monitored and assessed, in line with Quality Risk Management principles;

**This means:** when performing investigations, it's usually a good idea to determine the root cause of the issue so you can address and prevent recurrence and to determine the next course of action and how many resources you should allocate to it.

**Commonly found issues include**:

- No commentary on the Root Cause Analysis conclusions.
- Not using risk assessments to guide the investigation process
- CAPAs not established to address the root cause.
- Issues dismissed as minor, warranting no further investigation without justification or records.

Scenario: StrugglePharm has recently employed a new quality manager, she has 15 years of experience in quality management at PerfectoPharm, a large multinational and released sterile products for injection for supply into the Australian market. StrugglePharm has recruited her to release their medicines.

The new Quality Manager is:

a) Exempt from training and can release StrugglePharm's products into the market, because all release processes are the same.
b) Is the quality manager and quality managers don't need training.
c) Still required to complete training and prove competency despite all 15 years of experience because the quality systems are different.
d) Experienced and released sterile products and those are hard to release and therefore all products can be released by them.

# Training

## Consider:

- All quality systems are different and vary from site to site.
- Demonstrating capability especially when the task is critical to the manufacturing process may be warranted.
- Systems to track and trend training competency is a quick way to demonstrate your process capabilities.

# Clause 2.10 and 2.11

## Training

- 2.10 The manufacturer should provide training for all the personnel whose duties take them into production and storage areas or into control laboratories (including the technical, maintenance and cleaning personnel), and for other personnel whose activities could affect the quality of the product.
- 2.11 that besides the basic training on the theory and practice of the Pharmaceutical Quality System and Good Manufacturing Practice, newly recruited personnel should receive training appropriate to the duties assigned to them; that continuing training should also be given, and its practical effectiveness should be periodically assessed; that training programmes should be available, approved by either the head of Production or the head of Quality Control

**This means:** everyone needs training in the things that they do and everyone's understanding of the training should be tested every now and then and the training programmes are approved.

**Commonly found issues include:**

- No training curricula for complex tasks e.g. setting up and operating manufacturing equipment
- No training for personnel performing release for supply.
- No training competency assessment –physical steps of manufacturing, for example, gowning for high grade areas may require competency demonstration.

Scenario: StrugglePharm's warehouse was not temperature controlled but was temperature monitored. Summer temperatures inside the finished products warehouse reached 37°C on a daily basis and hourly records were kept. Products stored in the warehouse were non-sterile and a combination of listed and registered medicines in various dosage forms and some had a storage requirement of less than 25°C.

In this situation StrugglePharm should:

a) Average all temperatures recorded (day and night), find that it averaged 27.8°C and justify that 2.8°C over is acceptable, no further action was required.
b) Install some whirly birds on the top of the warehouse to vent the warehouse, find that it didn't change anything, no further action required.
c) Raise a deviation, investigate the impact of the warehouse temperatures, establish measures to limit the high temperature exposure of the temperature sensitive finished products, alert sponsors to the temperature deviation.
d) Start taking temperature readings only once a day and only in the morning. No further action required.

# Storage

## Consider that:

- Averaging temperatures doesn't justify the excursion in temperatures
- There may be some hotter or colder parts of the warehouse if temperature controls are beyond reach.
- Change controls are warranted when making alterations to the warehouse.

# Clause 3.19

## Storage

- that storage areas should be designed or adapted to ensure good storage conditions, that in particular, they should be clean and dry and maintained within acceptable temperature limits and that where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored:

**What this means:** qualify your storage areas and storage conditions for temperature and where needed, humidity and light.

Commonly seen at inspection:

- Humidity controls not in place for moisture sensitive starting materials like capsules.
- No thermal mapping of storage areas including warehouses and incubation devices.
- Seasonal variation in temperatures and humidity not considered.

Scenario: StrugglePharm was being inspected. During the inspection, management and the inspector reviewed a live gel clot test, the analyst was nervous, while reading the test result by inverting the tube to 180°, the analyst's hand start shaking. During tube inversion process the test tube of a positive product control sample, the clot breaks at about 90°,

# Record Keeping

## Consider

- Specific training tailored to data keeping and data integrity.
- Test results are to be recorded as they are.

In this scenario the records should indicate:

a) That it was a positive clot anyway because it was PPC.
b) That the clot broke at 90° and an investigation for the root cause may justify a retest.
c) That the PPC has never failed for that product before so record that the clot broke but was going to be a passing result.
d) Record that the test passed and have management sign off on this as pass.

# Clause 4.8

## Record Keeping

- Records should be made or completed at the time each action is taken and in such a way that all significant activities concerning the manufacture of medicinal products are traceable

**This means:** Record results and events as they are. Record actions as you do them so the activities are true and correct and can be relied upon to make decisions in the organisation.

**Commonly identified at inspection:**

- Manufacturing logbooks completed before the event takes place.
- Data integrity training not provided or outlined.
- The ‘obvious’ result is recorded but may not be reflective of the actual result.

Scenario: StrugglePharm manufactured some non-sterile registered liquid medicine for children. It was later found that the gear oil from the top mounted gearbox for the stirring motor leaked into the batch during manufacturing. Approximately 1.5l of gear oil leaked into the 2000L batch.

a. Raise a deviation and reject the batch. 1.5L of any oil from a gearbox that is not supposed to be in the product is unacceptable.
b. Justify that the 1.5L in 2000L dilution is acceptable, it's <1%.
c. Justify that the gear oil was "food grade" and therefore the batch is accepted for release.
d. Consider that rejecting this batch was the difference between sales targets being missed and negatively impacting sales bonuses.

# Cross Contamination

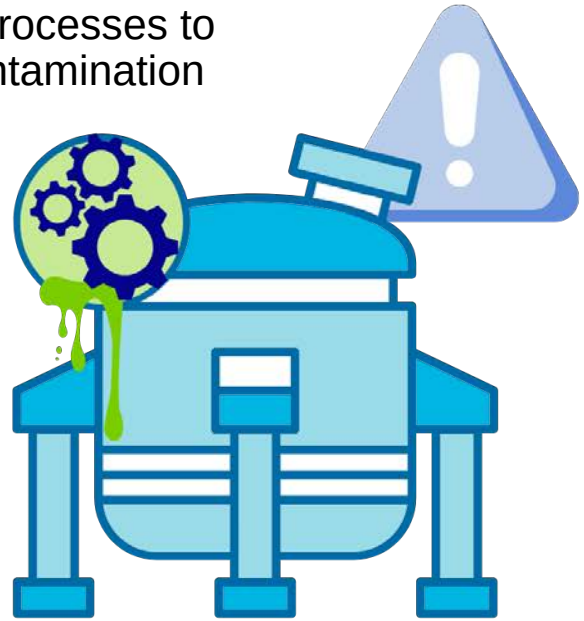
## Consider:

- Cross contamination is not limited to microbes.
- Performing risk assessments with your engineers to identify failure modes in your mechanical systems where events like this could occur.
- Control measures. Air pressures, powder containment equipment, process and procedural.

# Clause 5.19

## Cross Contamination

- Cross-contamination should be prevented by attention to design of the premises and equipment as described in Chapter 3 and that this should be supported by attention to process design and implementation of any relevant technical or organizational measures, including effective and reproducible cleaning processes to control risk of cross-contamination



**This means:** your facility as well as your procedures to manufacture product should be able to isolate products to ensure that product is not contaminated by your manufacturing processes or other product.

**Commonly seen at inspection:**

- Unsealed floors, split or broken vinyl.
- Cleaning processes not separated from manufacturing processes
- NPI process does not consider the products that are being introduced to the shared manufacturing lines
- Only microbial contamination is considered.

Scenario: StrugglePharm manufactures a product routinely and the 12-month stability testing for one batch has identified low assay (72.8%) of an active, the product has a 24-month shelf life.

a. Raise a deviation leave it open for 4 months without action.
b. Justify that because the deviation was not yet closed, that TGA Recalls was not required to be notified.
c. Add 40% more active to all subsequent batches without understanding the root cause of the issue.
d. Notify TGA recalls, perform the root cause analysis of the problem and action according to the root cause analysis.

# Trend Investigations

## Consider::

- Trending isn't limited to just finished product testing.
- This data can and should be used in PQRs.

# Clause 6.35

## Investigating Trends

Out of specification or significant atypical trends should be investigated, that any confirmed out of specification result, or significant negative trend, affecting product batches released on the market should be reported to the relevant competent authorities and that the possible impact on batches on the market should be considered in accordance with Chapter 8 of the GMP Guide and in consultation with the relevant competent authorities


**What this means:** when unusual trends are identified that impact product batches, investigate the trends and consider the impact on product in the market.

**Commonly seen at inspection:**

- Trending not being performed
- Trend data not analysed
- Data generated from PQRs not used to aide investigations of this nature
- Poorly defined procedures for what constitutes a trend

Scenario: A customer complaint was received at StrugglePharm of a bottled capsule product. The complaint was that the screw top lid was not applied to the bottle and when the heat shrink seal on the lid was removed, the cap falls off with the heat shrink.

In this situation StrugglePharm should:

a. Investigate lid torquing equipment as a probable point of failure, perform a risk assessment, determine the root cause, and establish preventative measures to bracket the extent of the issue to other batches.
b. Dismiss the complaint as unjustified, the complainant only wanted a freebie, and we gave them a replacement.
c. Keep the customer complaint information in an uncontrolled excel spreadsheet kept on the quality manager's Windows desktop.
d. Establish a rule that complaints are not considered justified until 3 or more of the same complaint for the same batch is received.

# Complaints

## Consider that:

- Justified complaints often indicate a quality system has failed.
- Dismissing a complaint as unjustified should be supported.
- Performing due diligence checking of systems whether the complainant has provided enough data or not could save the next batch and support the conclusions made of the investigations process.

# Clause 8.9

## Complaints

- When a quality defect investigation is initiated, procedures should be in place to address at least the following: The assessment of the risk(s) posed by the quality defect, based on the severity and extent of the quality defect and The decision-making process that is to be used concerning the potential need for risk-reducing actions to be taken in the distribution network, such as batch or product recalls, or other actions and The identification of the potential root cause(s) of the quality defect.

**What this means:** perform risk assessments once a complaint is received and if considered justified it is likely that something has escaped your quality system, or the quality system is lacking. Assess the likelihood that this may have to other batches manufactured to determine the next steps

**Commonly seen at inspection:**

- Complaints dismissed as unjustified without rationale
- Complaint risk assessments not performed
- Impact to other batches not assessed
- No consideration for all products manufactured since the complaint batch

# Audit Trails

Scenario: A new filter testing unit has arrived on site at StrugglePharm. Individual bubble point test set points are able to be to altered and the records of tests can be deleted by StrugglePharm's Quality Manager and Production Manager:

a. Ensure that access to alter setpoints is limited and recorded and proceduralised. Remove all abilities to delete test runs and records and review audit trails regularly for unusual events logged in the system.
b. They are both members of management and should have access to change set points and delete records of tests.
c. Activating the audit trails are cumbersome and takes too much time to review. Disable the audit trails so we don't have to review them.
d. "Review" the non-human-readable string of error codes on completion of each batch and tick the "all ok box" in the batch docs.

## Consider:

- System capability and criticality of the data that is being generated.
- Using the Audit Trails in a meaningful way.

# Annex 11 § 9

## Computerised systems
## Audit Trails

- Consideration should be given, based on a risk assessment, to building into the system the creation of a record of all GMP-relevant changes and deletions (a system generated "audit trail"). For change or deletion of GMP-relevant data the reason should be documented.

  Audit trails need to be available and convertible to a generally intelligible form and regularly reviewed.


**This means:** make sure your computerised systems' audit trails are activated and reviewed and you understand what you are reviewing.

**Commonly seen at inspection:**

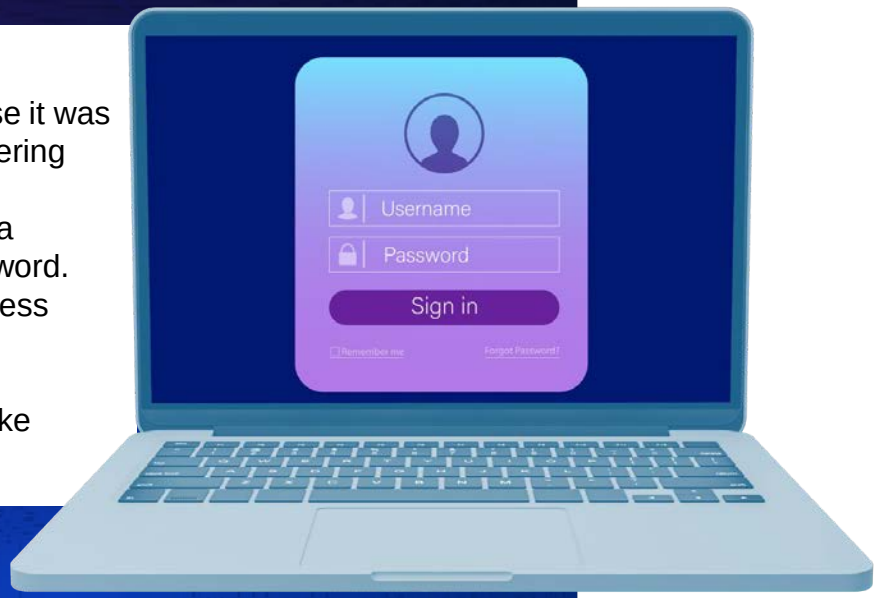
- Audit trails not active on computerised systems.
- Audit trails available but not reviewed.
- Audit trails are 'reviewed' but there is no procedure to outline what is and what is not acceptable.
- Some audit trails generated are not interpretable, e.g. a string of codes

# Computerised Systems Security

Scenario: A new automatic filling machine has arrived. Configuration controls on the unit are protected by user ID and passwords and each user could be assigned individual privileges. These were included in the operational qualification, however, there were no procedures to describe the controls in place to use the filler.

In this case, StrugglePharm should:

a. Not need to qualify system security because it was already done on a different but similar blistering line we previously bought.
b. Use the system as is because only the area manager and the engineer know the password.
c. Maintain records of the users and their access levels and allow access depending on user need and training level.
d. Share the username and passwords to make record keeping easier.




## Consider:

- Actions performed should be traceable to an individual
- User access should be limited to only the functions needed

# Annex 11 § 12.1

## Computerised Systems Security

- Physical and/or logical controls should be in place to restrict access to computerised system to authorised persons. Suitable methods of preventing unauthorised entry to the system may include the use of keys, pass cards, personal codes with passwords, biometrics, restricted access to computer equipment and data storage areas.

**This means:** restrict access to your systems and don’t share passwords and make data entry uniquely identifiable to one person and lock the system clock

**Commonly seen at inspection:**

- Shared user log in.
- Operating Systems’ Systems Clock (Windows) and dates not locked.

Scenario: StrugglePharm is looking to migrate the paper based quality system to an eQMS.

As this was a new system, they should:

a) Raise a change control, assess the risks of implementing the new system and establish mitigation steps for each risk identified before implementation.
b) Introduce the new eQMS using a change control that had no relevant information or risk assessment.
c) Document input into the change control from various departments using post-it notes and sticking them to the change control.
d) Risk assessments not required; this is a widely adopted eQMS in the industry.

# Risk Assessments for Validation

## Consider:

- Risk should be the driver behind most decisions made in the organisation.
- There may be unintended consequences if one system is changed without consideration of another system

# Annex 15 § 1.7

## Risk Assessments for Validation

- A quality risk management approach should be used for qualification and validation activities. In light of increased knowledge and understanding from any changes during the project phase or during commercial production, the risk assessments should be repeated, as required. The way in which risk assessments are used to support qualification and validation activities should be clearly documented.

**This means:** Understand if there are risks with a proposed change you are about to make. As the knowledge of the risk expands, consider repeating your risk assessments using the new knowledge you've gained.

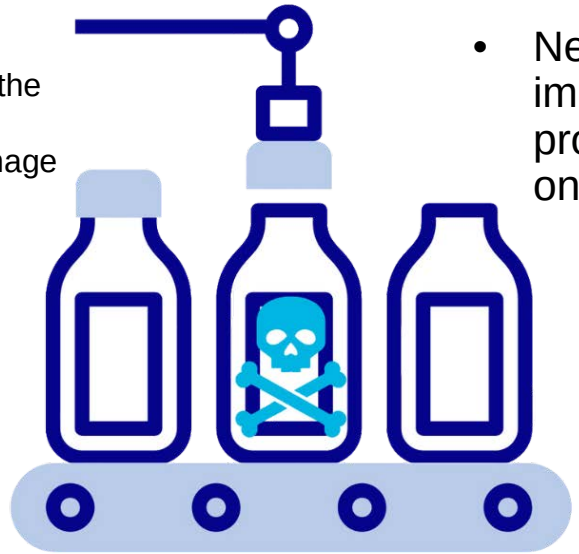
**Commonly seen at inspection:**

- No risk assessments performed for changes to assess impact to other processes.
- Risk assessments assessed as minor without justification.
- No change controls at all for process changed that were assessed as 'minor changes' in someone's head.
- Building work change controls do not consider impact to existing operations.

Scenario: StrugglePharm has taken on a new contract to manufacture a cytotoxic substances on site and they will be making it on a shared line with listed products.

Before introducing this product into the shared manufacturing processes, StrugglePharm should:

a) Start manufacturing as soon as possible, it's a big contract.
b) Not bother with assessing the risk of introducing this product into the existing, shared processes, we've done cleaning validations for other products.
c) Raise a change control and record information provided from various departments using post-it notes and sticking them to the pages of the change control.
d) Raise a change control, assess the associated risks and manage the risks that are not acceptable or require remediation.



# Annex 15 § 11.2 and 11.4 changes

## Consider:

- Changing one process may inadvertently impact another.
- Risk assessments can identify unexpected issues.
- Experts in different areas may view a change differently, seek their opinion.
- New Product Introduction plays an important part to ensuring that your products do not contaminate one another.

# Annex 15§11.2 and §11.4

## Changes

- Annex 15 §11.2 and § 11.4 Written procedures should be in place to describe the actions to be taken if a planned change is proposed to a starting material, product component, process, equipment, premises, product range, method of production or testing, batch size, design space or any other change during the lifecycle that may affect product quality or reproducibility. And Quality risk management should be used to evaluate planned changes to determine the potential impact on product quality, pharmaceutical quality systems, documentation, validation, regulatory status, calibration, maintenance and on any other system to avoid unintended consequences and to plan for any necessary process validation, verification or requalification efforts.

**What this means:** changes to your processes and premises need change controls. The change controls should be evaluated using risk assessments to determine the effort and resources that they may need and to determine if they may impact other processes unintentionally.

**Commonly seen at inspection:**

- No risk assessments performed for changes to assess impact to other processes.
- Risk assessments assessed as minor without justification.
- No change controls at all for process changed that were assessed as ‘minor changes’ in someone’s head.
- Building work change controls do not consider impact to existing operations.

# 12 out of 12. Full Marks!

- Thank you for your participation today!
- StrugglePharm can continue manufacturing their quality product thanks to your logical and well thought out quality responses.

# A final word on common deficiencies

- All the ‘wrong answers’ that you **didn’t select** for StrugglePharm were real examples of answers provided at inspection.
- These were ***common*** deficiencies cited at inspection.
- Please take this presentation back to your organisations and try to make these deficiencies less common.

# Questions?

Scan this QR code with your device to submit a question

GMP FORUM 2024

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration