Australian Government
Department of Health
Therapeutic Goods Administration

GMP Clearance

Common deficiencies

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2021 GMP FORUM

13/05/2021

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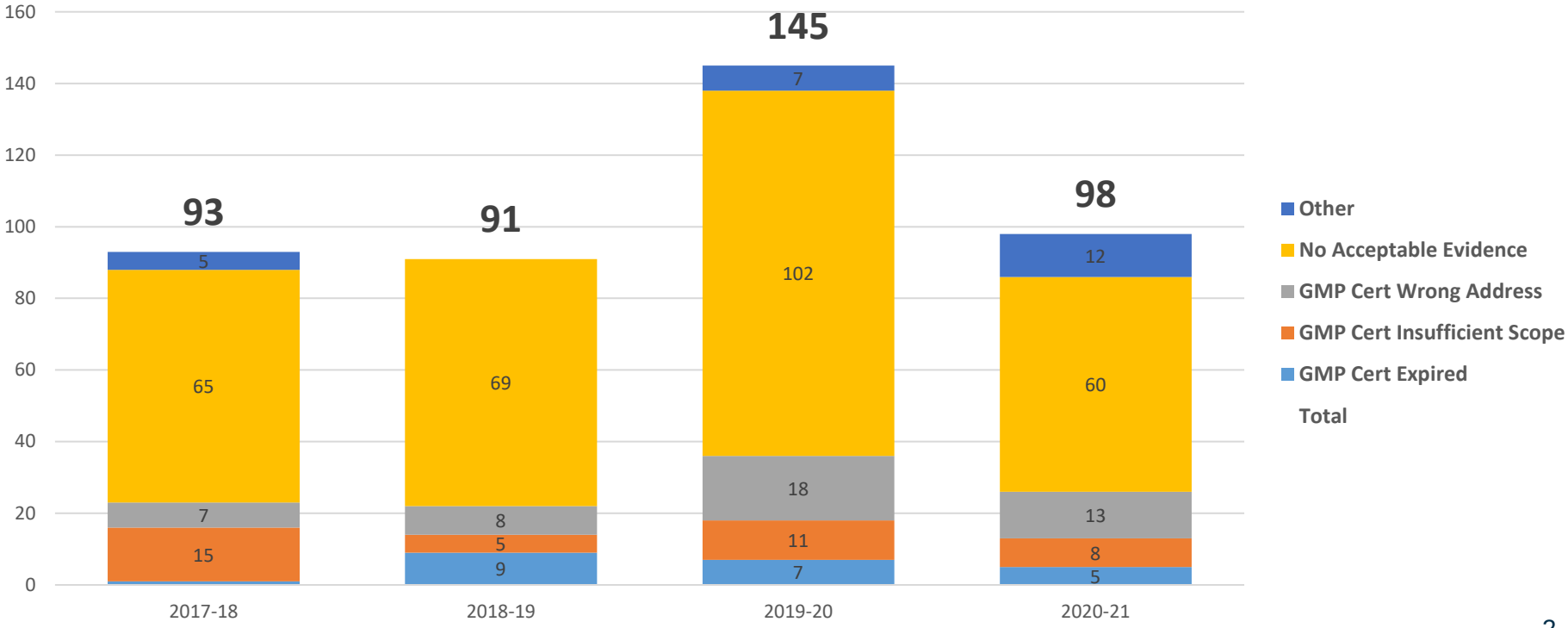
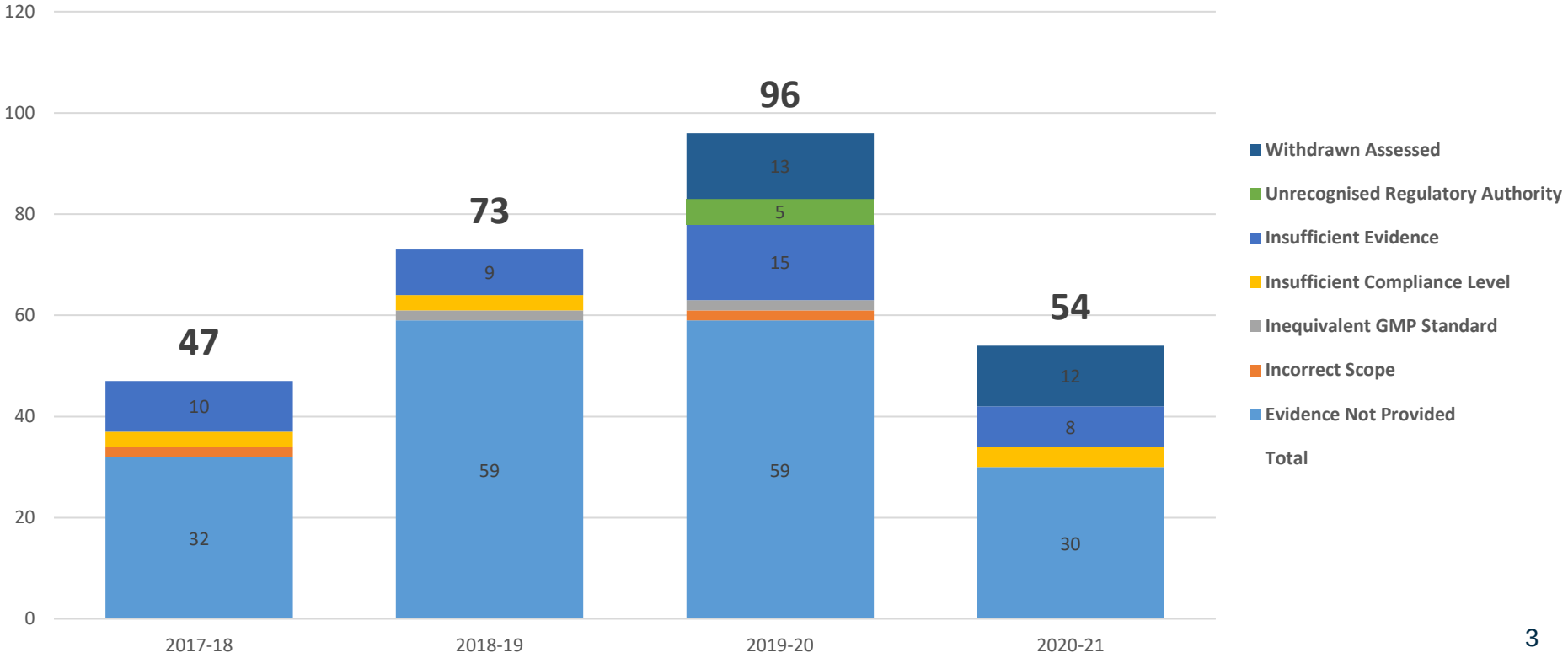
Overview

- Not issued applications
- GMP Agreements
- Release For Supply
- Other common issues

Not issued – MRA Pathway



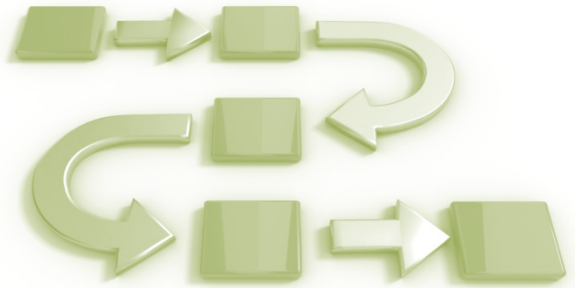
Not issued – CV Pathway



GMP Agreements – common issues

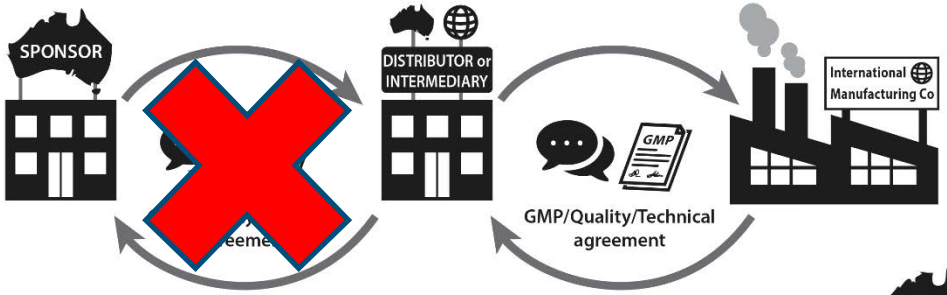
- Is not current and is outside the review period typically applied to GMP documentation
- The parties are not clearly identified and have not signed
- The roles and responsibilities are ambiguous for critical aspects
- Terminology used is not relevant for the Australian market
- Australian Sponsor does not meet the requirements of PIC/S clause 1.11 for PQR input and review
- Oversight of the shipping of the product to Australia between the parties in the agreement are not clearly documented including provisions for temperature excursions and investigations

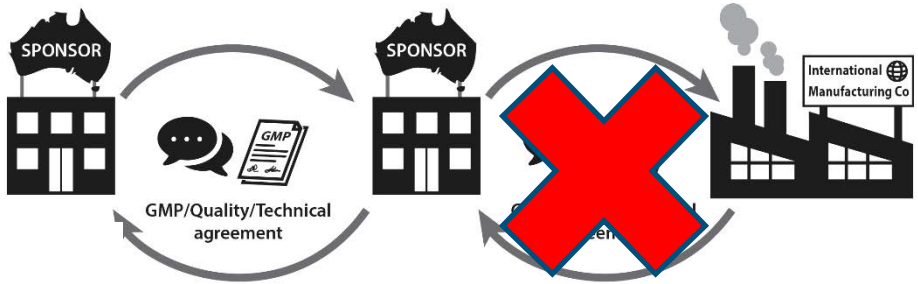
GMP Agreements



- Post market responsibilities of the Australian sponsor are not clearly outlined (i.e. recalls, complaints) including the flow of information between the relevant parties
- The agreement does not cover the dosage forms or steps of manufacture applicable to the GMP clearance
- There's no provision that the sponsor will provide the manufacturer with marketing authorisation requirements/variations for Australia
- No provision for sponsor's approval of product labels

Not all agreements in the supply chain are provided





Case Study

1. The requirements of clause 7.11 that a contract should be drawn up between the contract giver and acceptor which specifies their respective responsibilities and communication processes and that all arrangements for outsourced activities must be in accordance with regulations in force and the Marketing Authorisation for the product were not fully met. Specifically:
    a. No specific details relating the product(s) covered by the agreement were included in the contract. Details of product names, formulations, specifications and ARTG numbers were not included.
    b. The contract did not specifically outline how all relevant aspects of the Market Authorisation would be provided to the contract acceptor. The provision of 'TGA listing certificates' does not adequately convey all necessary conditions, orders and standards that are relevant to the production and supply of medicinal products to Australia.
    c. The contract states that the allocation of the expiry date and storage conditions is the responsibility of the CG; however, the contract does not clearly state that the CG must provide the CA with suitable evidence to justify the allocated expiry date and conditions.
    d. The responsibility for the recording and investigation of complaints is not defined.
    e. The responsibility for the initiation of product recalls, including recording, investigation, root cause analysis and CAPA is not specified.
    f. The contract does not outline the MAH's responsibility for provision of information, or approval for the Product Quality Review.
    g. The responsibility for intermediate (bulk) stability is not defined within the document.
    h. The contract does not specify the manufacturing address of the site.
    i. The contract does not have a defined review period
    j. The GMP guide referenced in the contract are out of date, and were superseded in 2009.

Release For Supply

- Release documents provided are system interface procedures (i.e. SAP)
- Not all documents related to the release/disposition of product are provided
- No details about the process of release and how the Australian MA requirements are considered
- No clarity on terminology differences
- Disconnect between site procedures and GMP agreements (i.e. release under quarantine)

Other issues commonly seen

- Inspection coverage was insufficient for the buildings/scope of the Australian product / MA
- Regulatory actions details insufficient
- No appendices provided (i.e. SMF or VMP validation schedule/status)
- No explanation as to why certain documents were not provided. No rationale or justification for certain requests
- Latest documents not provided after submission (i.e. latest PQR, inspection report etc)


Q&A

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