



Australian Government  
Department of Health  
Therapeutic Goods Administration

# Current inspection trends

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**TGA** Health Safety  
Regulation

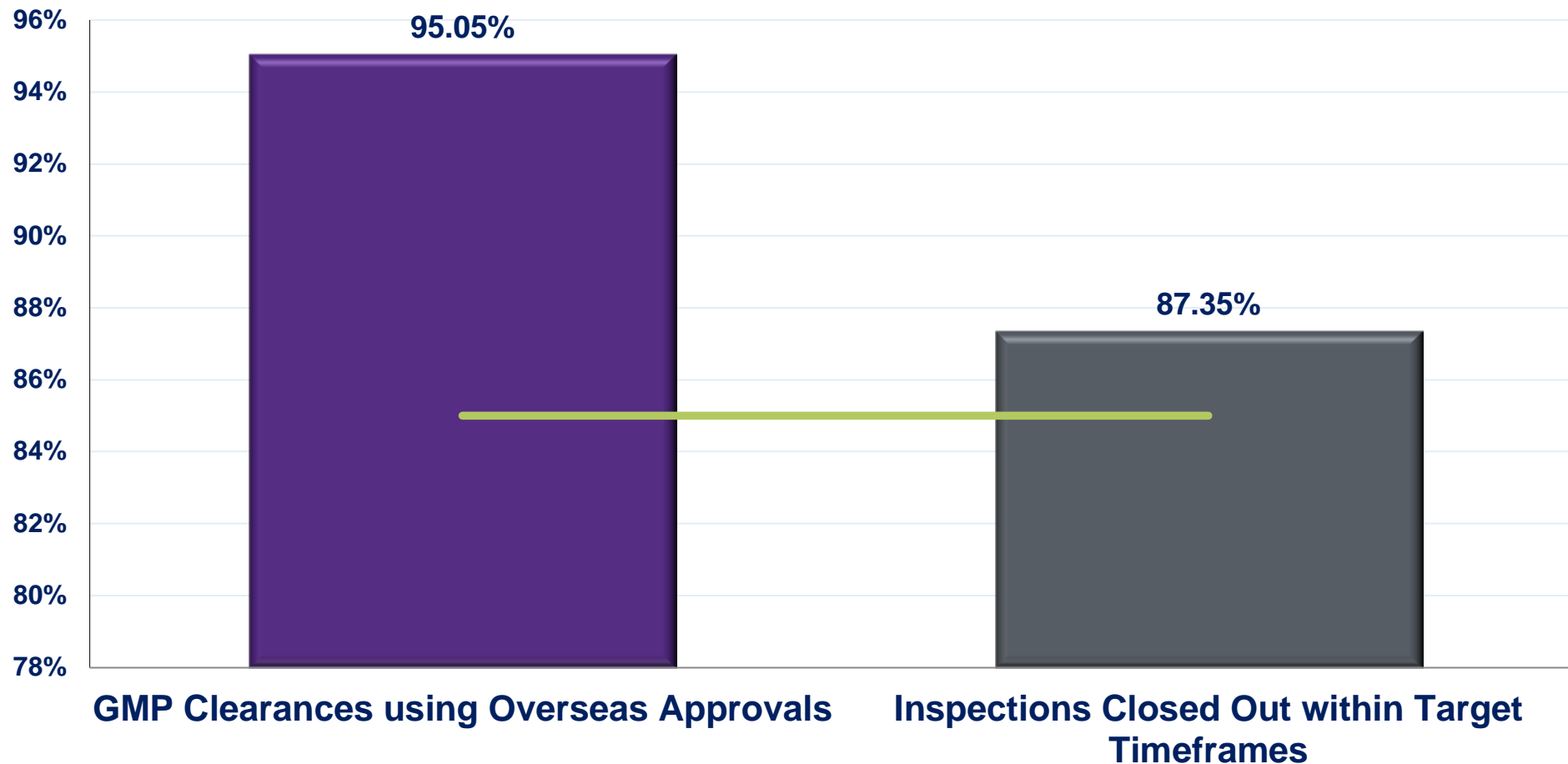
# Presentation overview

- TGA Portfolio Budget Statement performance
- Outcome of Inspections
- 2016 Inspections trends
- 2015 Inspection trends
- Close out process

# Portfolio Budget Statement

- KPI- Inspections closed out within target timeframes
- The target is 85%

# Portfolio Budget Statement – 15/16 financial year



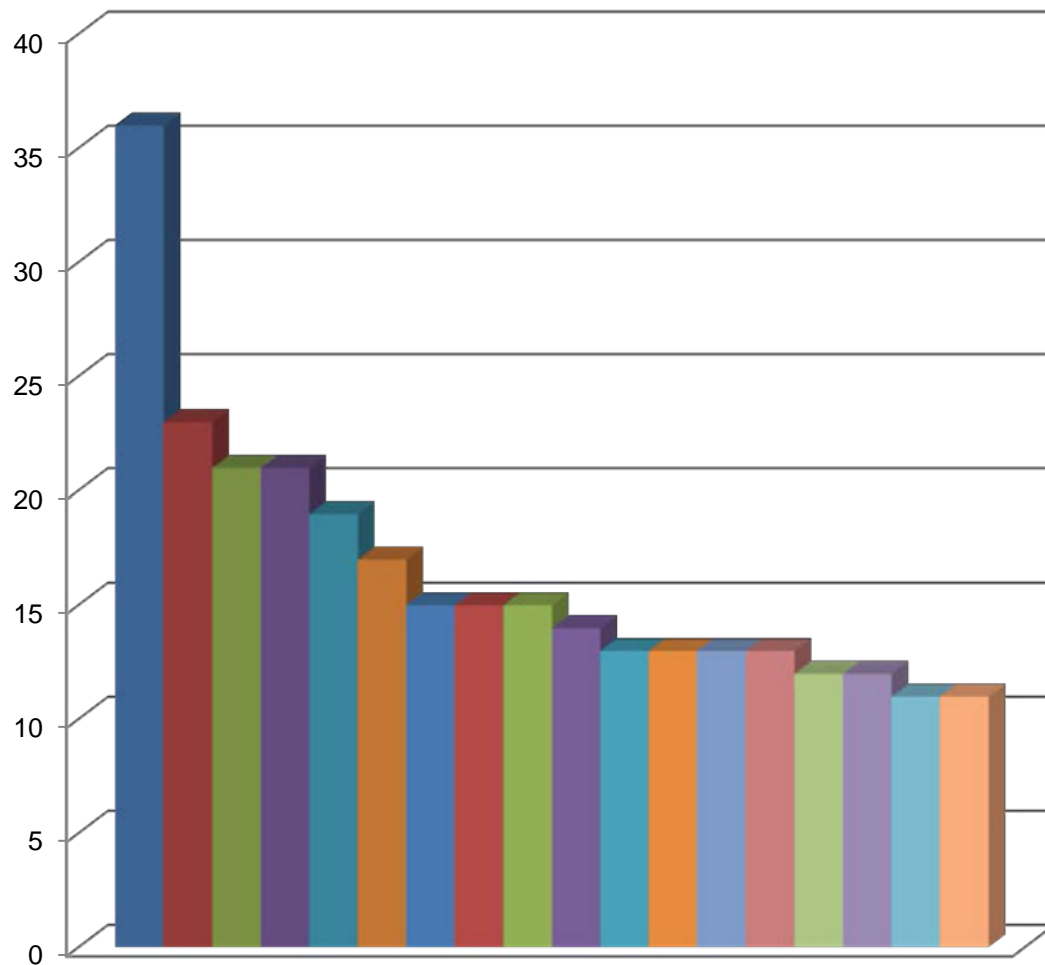
# Current inspection trends

Most common types of deficiencies in 2016 to date related to

- Poor investigations
- Computerised systems
- Validation
- QMS
- Quality control

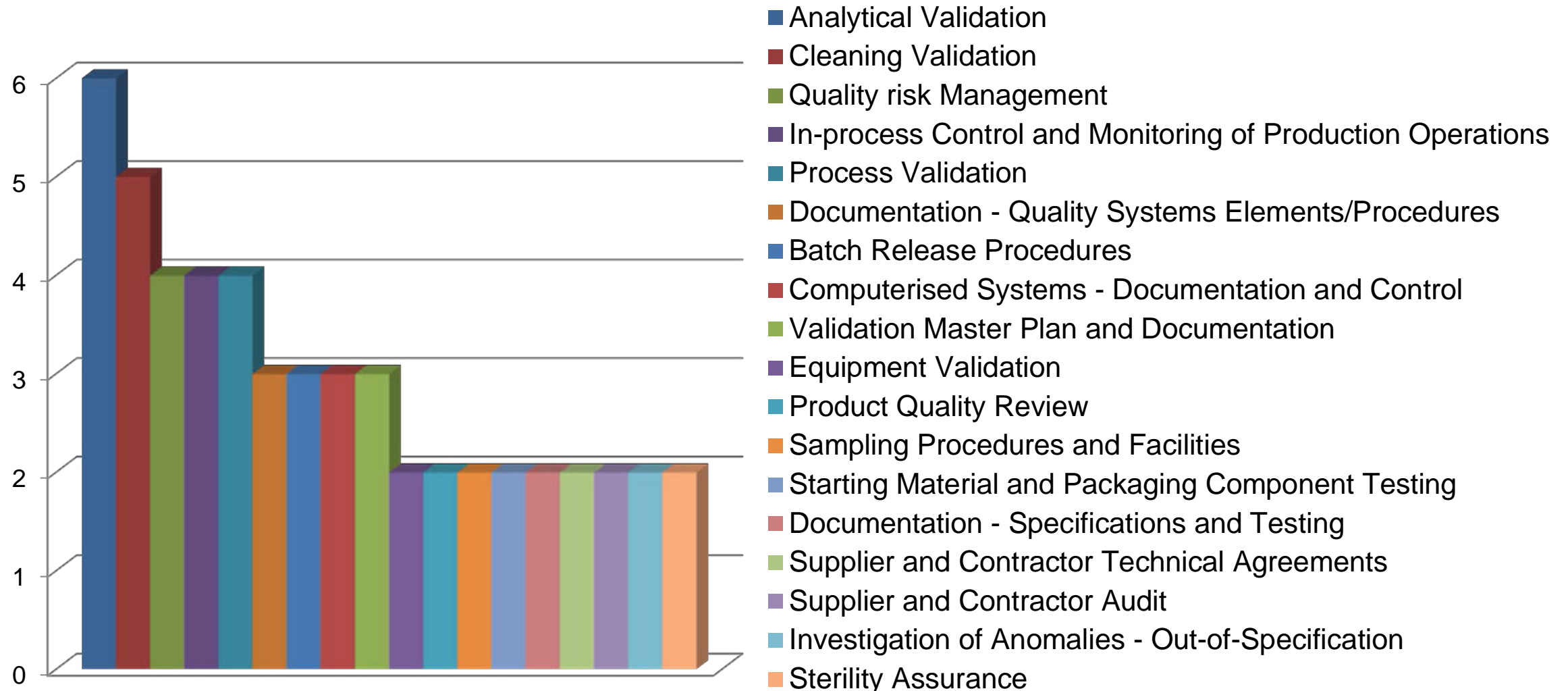


# 2015 Overseas inspections: Top 10 most occurring deficiencies

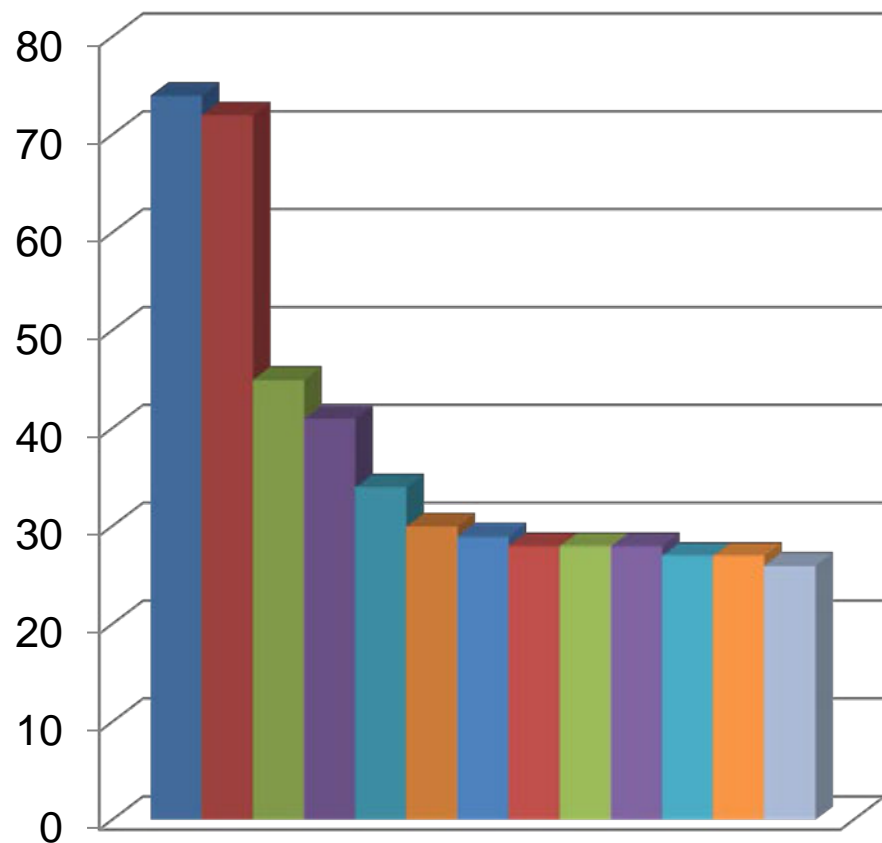


- Documentation - Quality Systems Elements/Procedures
- Quality risk Management
- Calibration of Measuring and Test Equipment
- In-process Control and Monitoring of Production Operations
- Equipment storage - contamination (potential)
- Complaints and Product Recall
- Investigation of Anomalies
- Documentation - Manufacturing
- Equipment Validation
- Product Quality Review
- Change Control
- Personnel Issues - Training
- Sampling Procedures and Facilities
- Starting Material and Packaging Component Testing
- Design and Maintenance of Premises
- Status labelling - Work in Progress, Facilities, Equipment
- Batch Release Procedures
- Analytical Validation

# 2015 Overseas inspections: Top 5 major only deficiencies



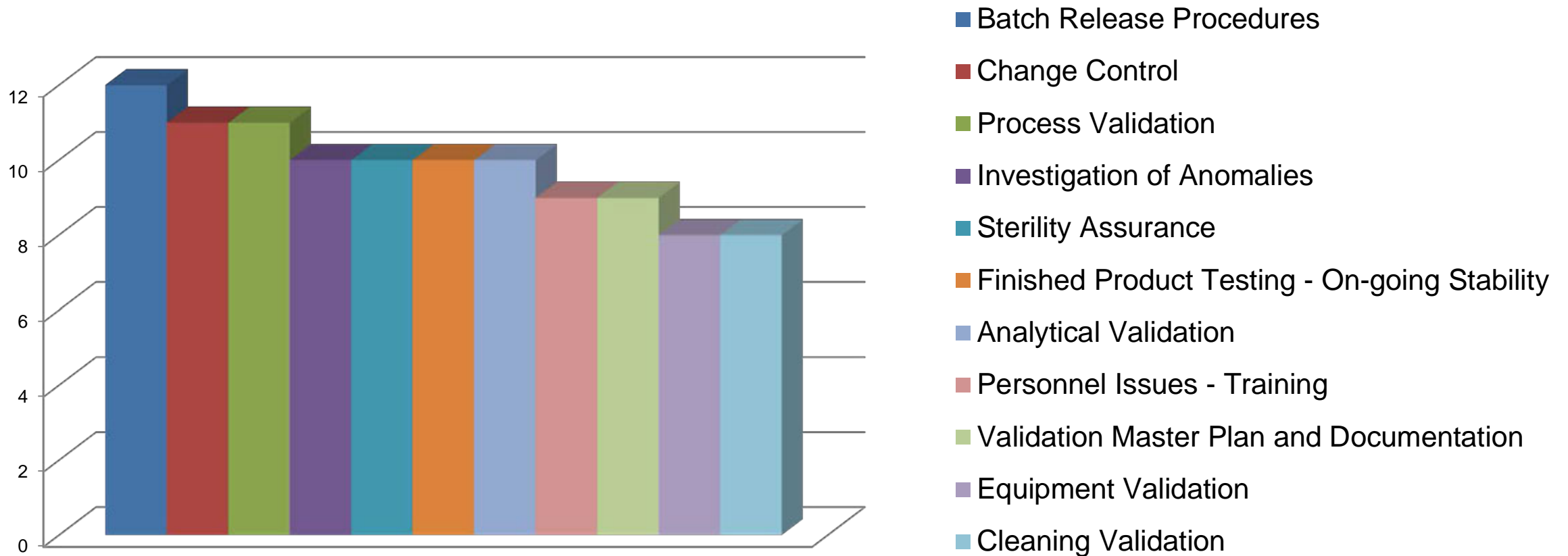
# 2015 Domestic inspections: Top 10 most occurring deficiencies



- Management and control of misc records
- Documentation - Quality Systems Elements/Procedures
- Personnel Issues - Training
- Complaints and Product Recall
- Change Control
- Investigation of Anomalies
- Quality risk Management
- Equipment Validation
- Product Quality Review
- Calibration of Measuring and Test Equipment
- Validation Master Plan and Documentation
- Personnel Issues -Duties of Key Personnel
- Supplier and Contractor Technical Agreements



# 2015 Domestic inspections: Top 5 major only deficiencies



# Current inspection trends

## New close out process

- Issue post-inspection letter.
- Responses received on a close out template with a CAPA plan.
- Up to 3 responses then escalate to an internal review process.



# Current inspection trends

## New close out process

- Objective evidence requested only under certain situations e.g. initial, recurring issues
- Final inspection report sent once the inspection responses are completed
- Addition of time at the next inspection for A2 and A3 manufacturers to review the evidence from the CAPA PLAN.



# Current inspection trends

## Summary

- More than 85% inspections are closed out on time
- Types of deficiencies have been provided for 2015 and 2016
- The new close out process will facilitate inspections are closed out in a more timely manner.



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