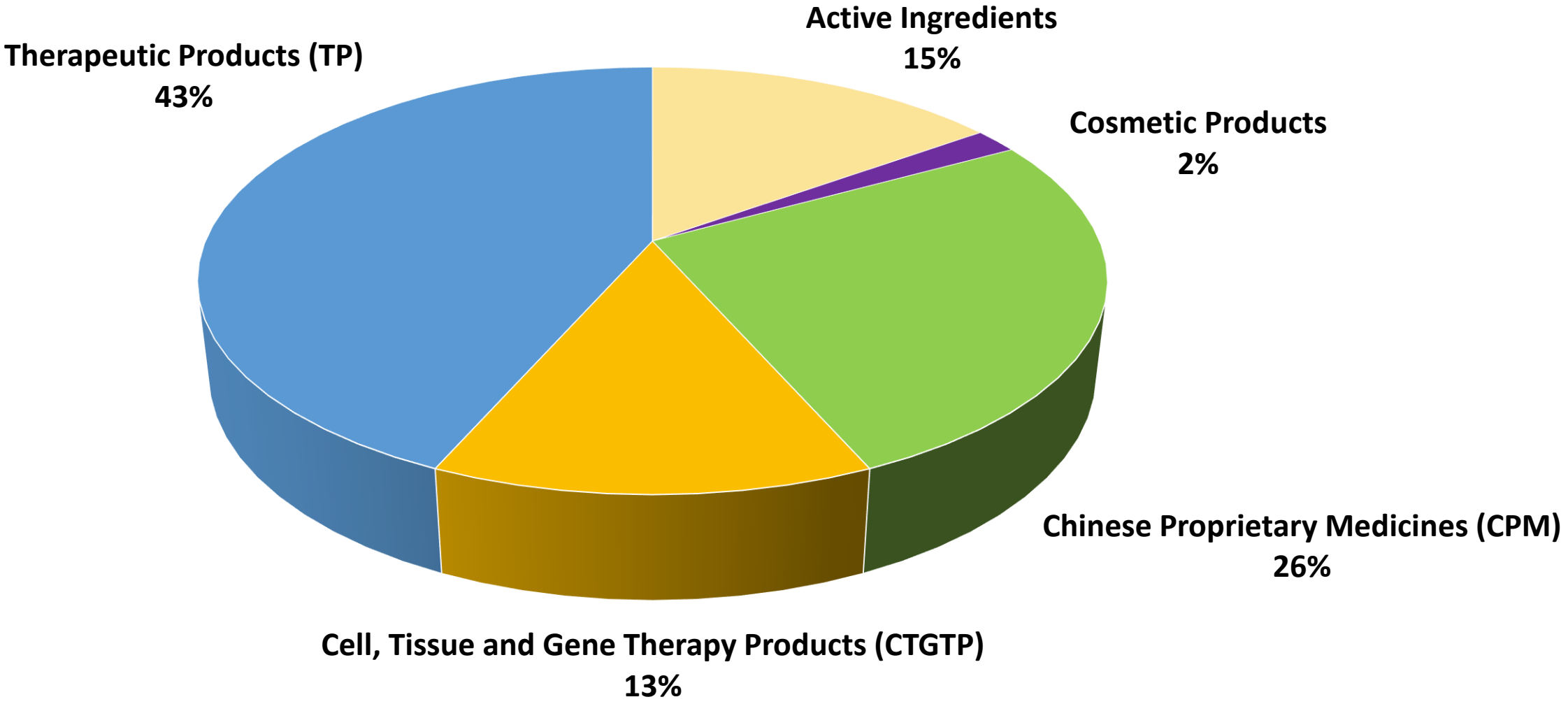
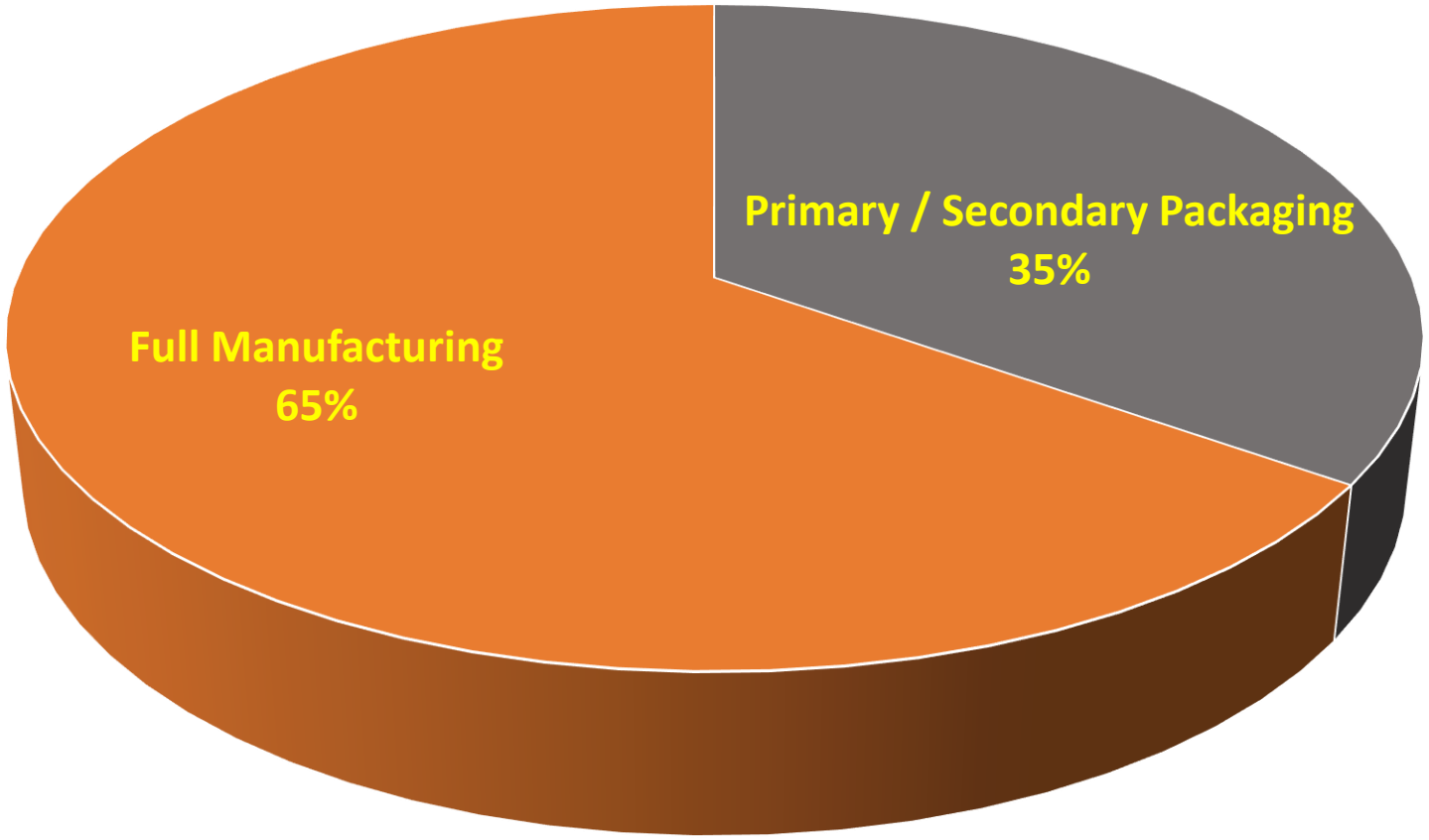
TRENDING OF GOOD MANUFACTURING PRACTICE (GMP) DEFICIENCIES OF MANUFACTURERS 2025

All Rights Reserved, Health Sciences Authority

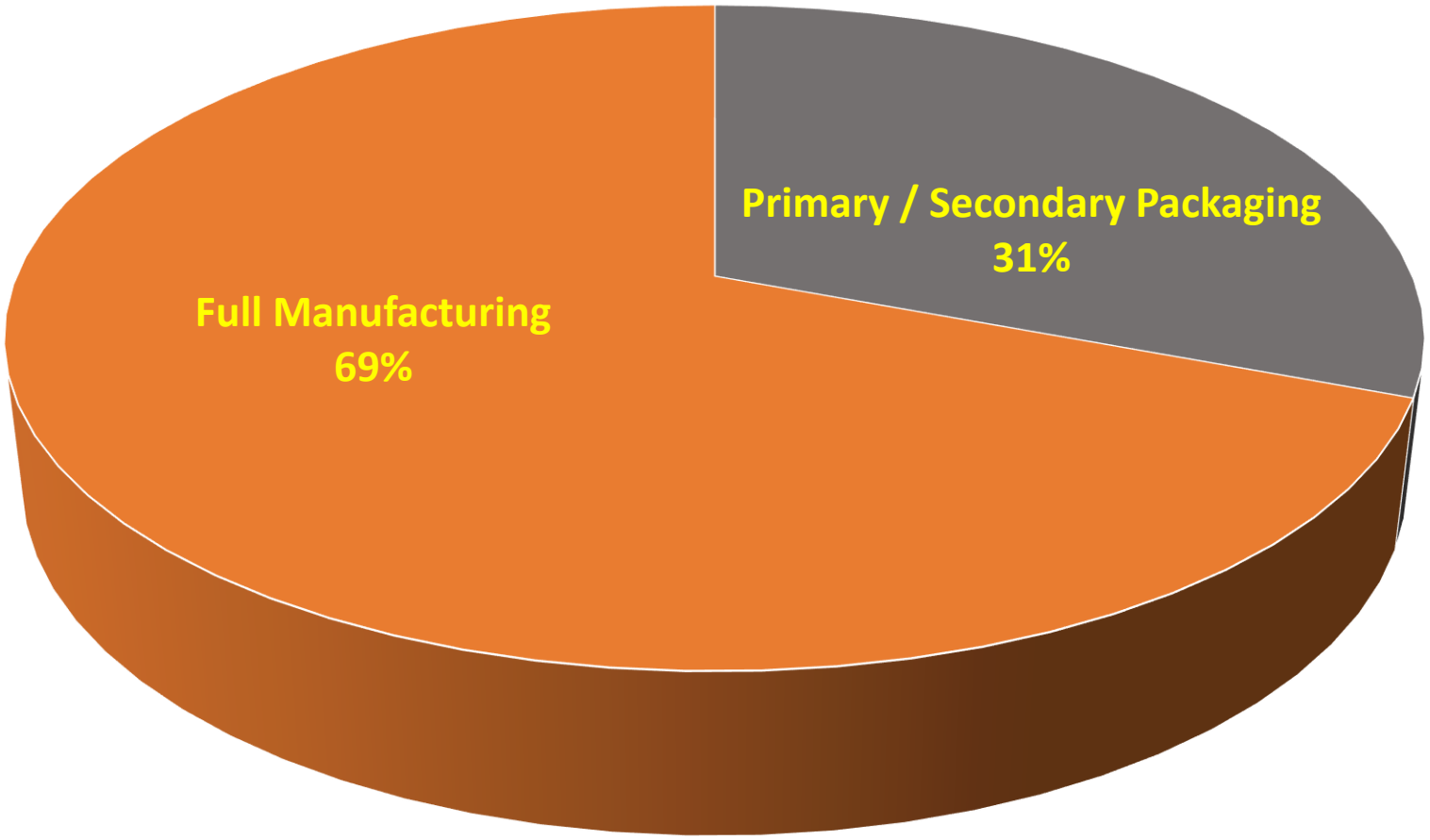
Profile of Manufacturers for Inspections Conducted in 2025



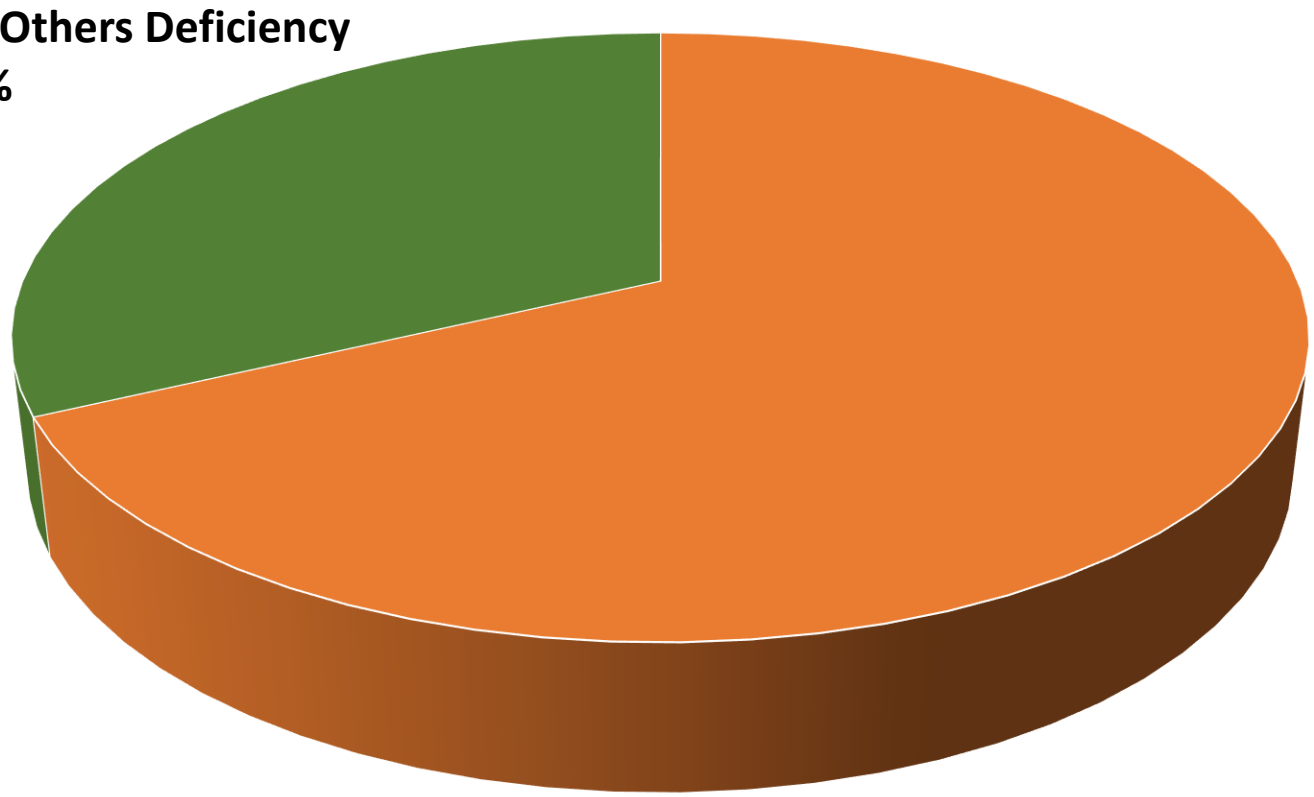
Therapeutic Products Manufacturers Inspected in 2025



Chinese Proprietary Medicine Manufacturers Inspected in 2025

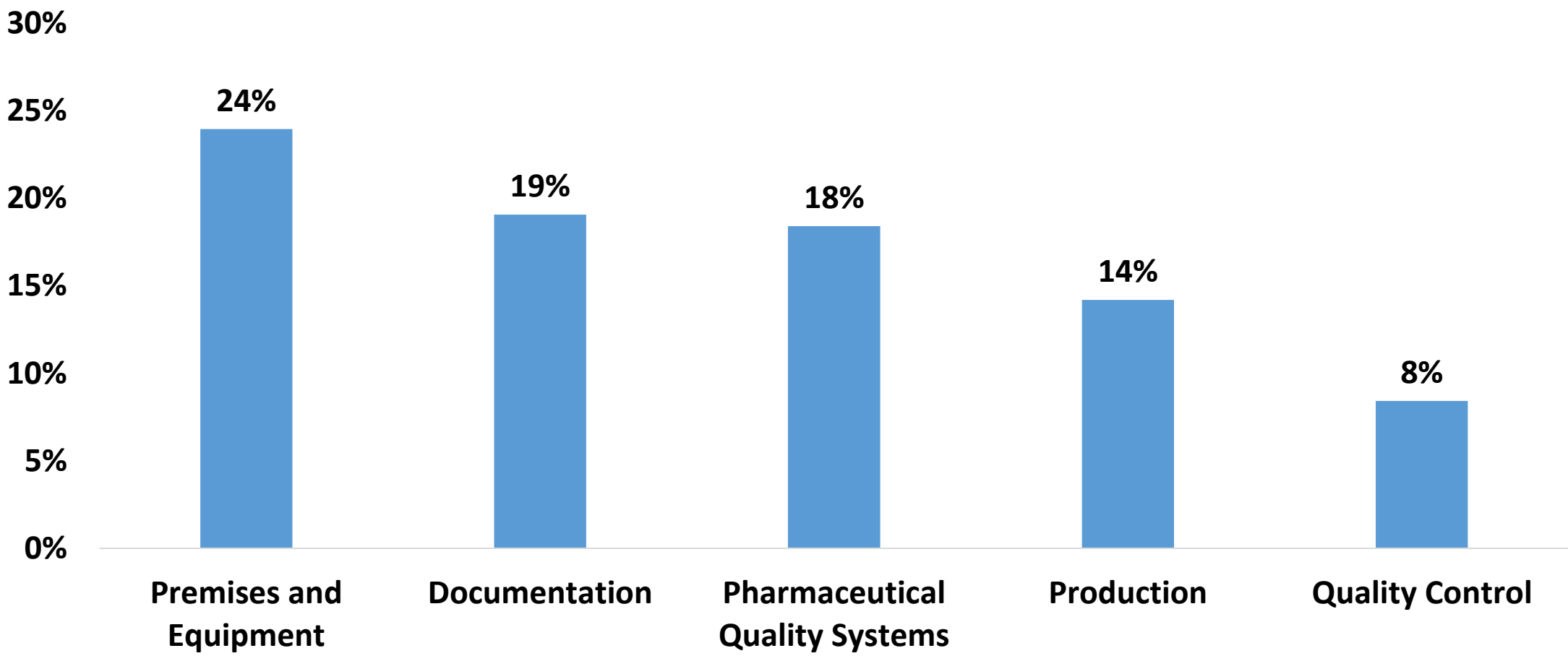


Distribution of GMP Inspections Outcomes by Deficiency Severity in 2025

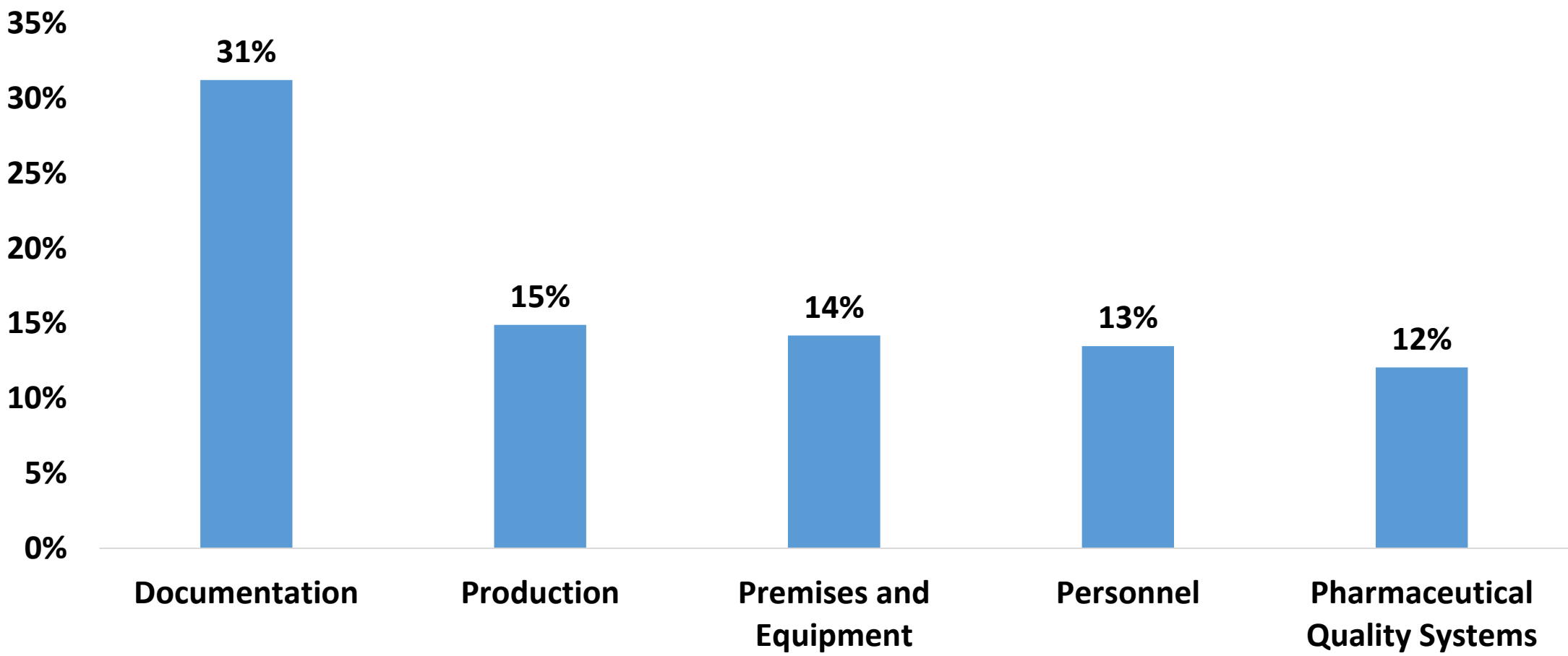


Note: Inspection with ≥ 1 Critical Deficiency : 0%, Inspection with No Deficiency : 0%

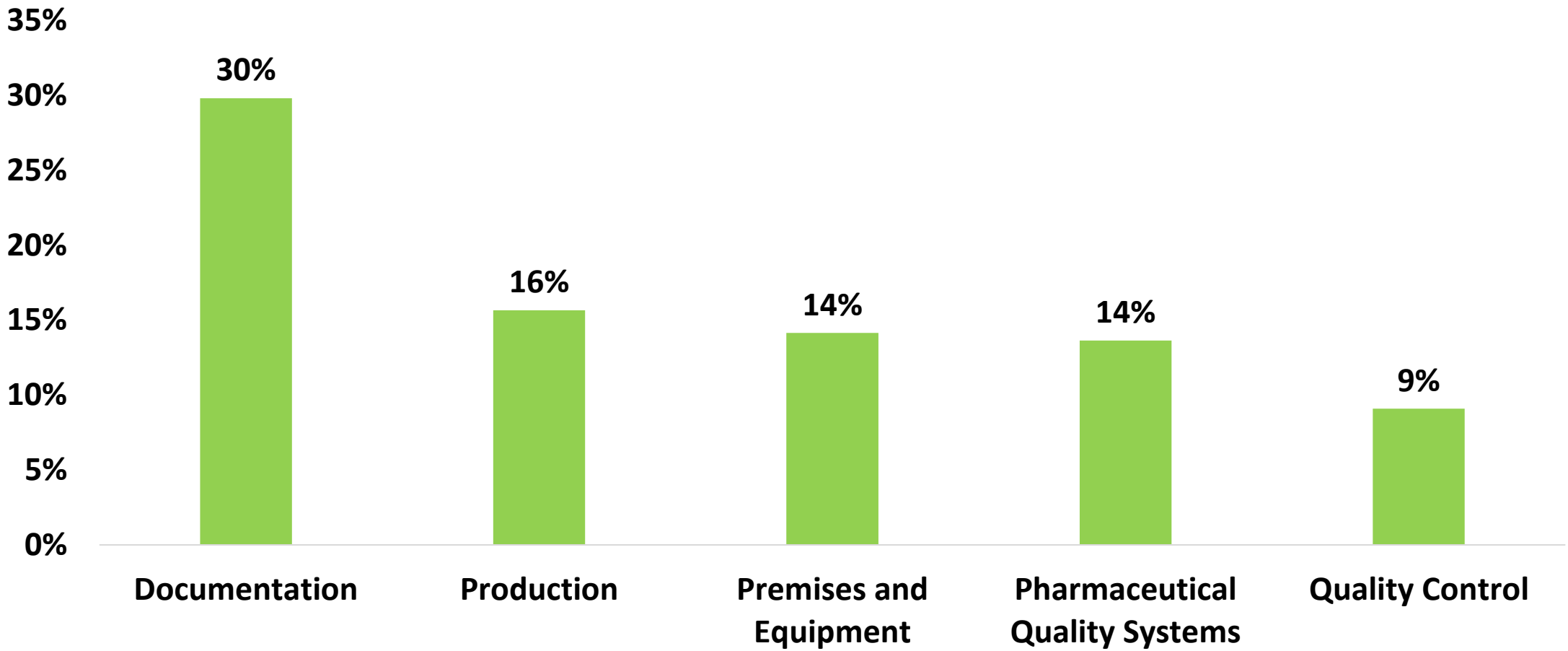
Top 5 GMP Deficiency Categories for Full Manufacturers of Therapeutic Products in 2025



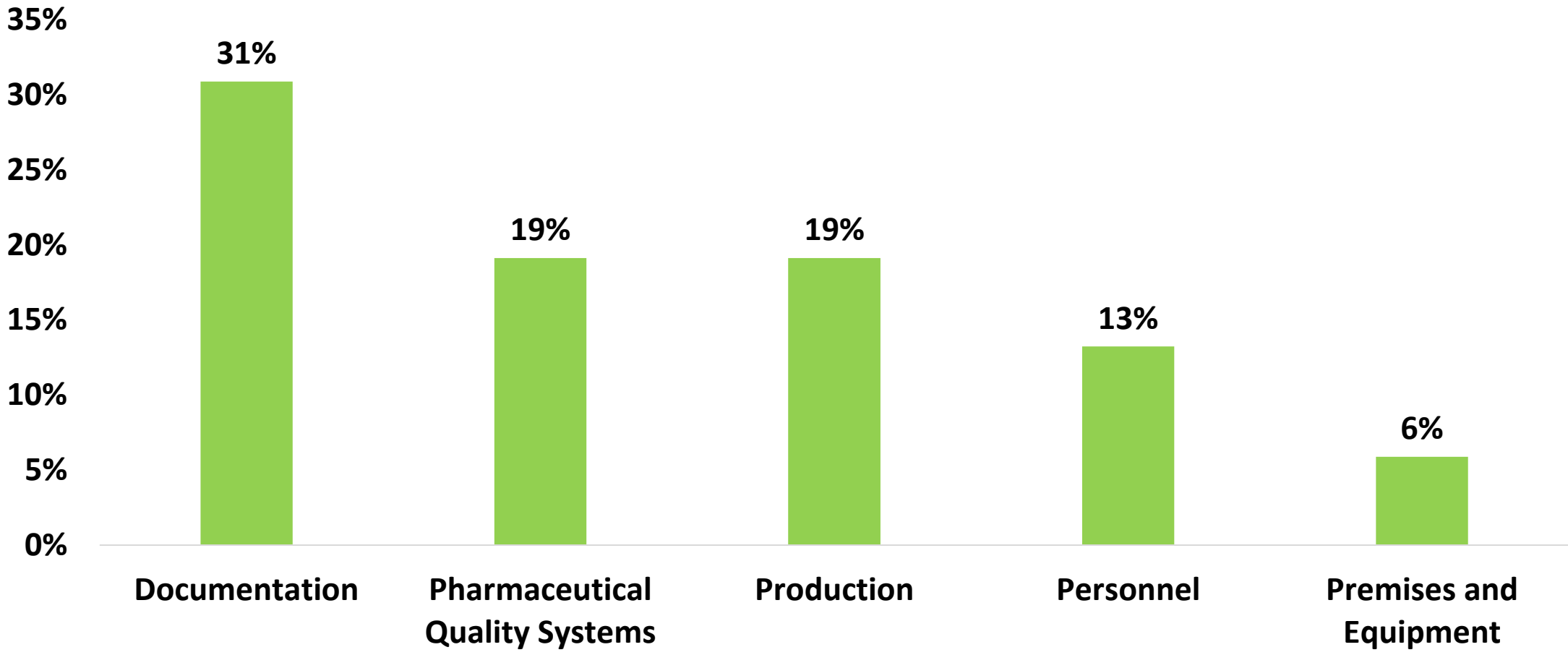
Top 5 GMP Deficiency Categories for Packagers of Therapeutic Products in 2025



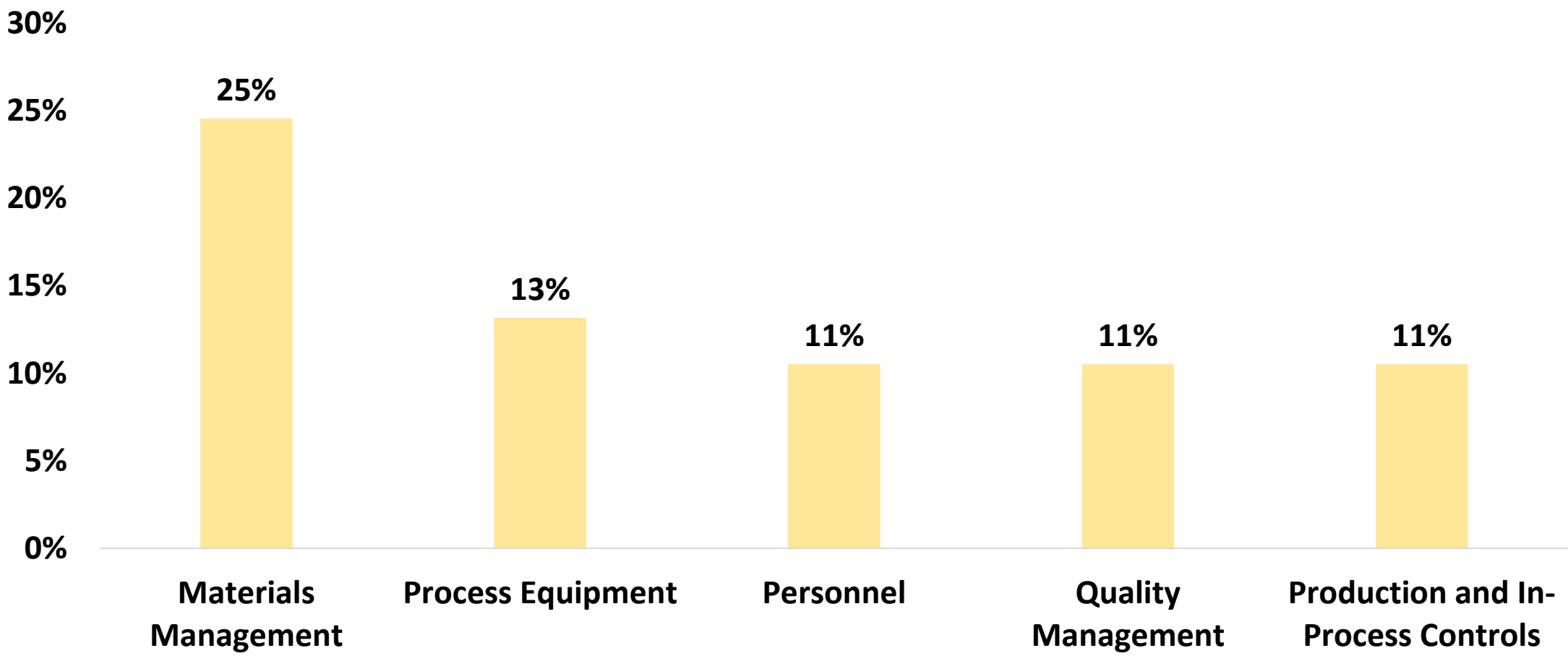
Top 5 GMP Deficiency Categories for Full Manufacturers of Chinese Proprietary Medicines in 2025



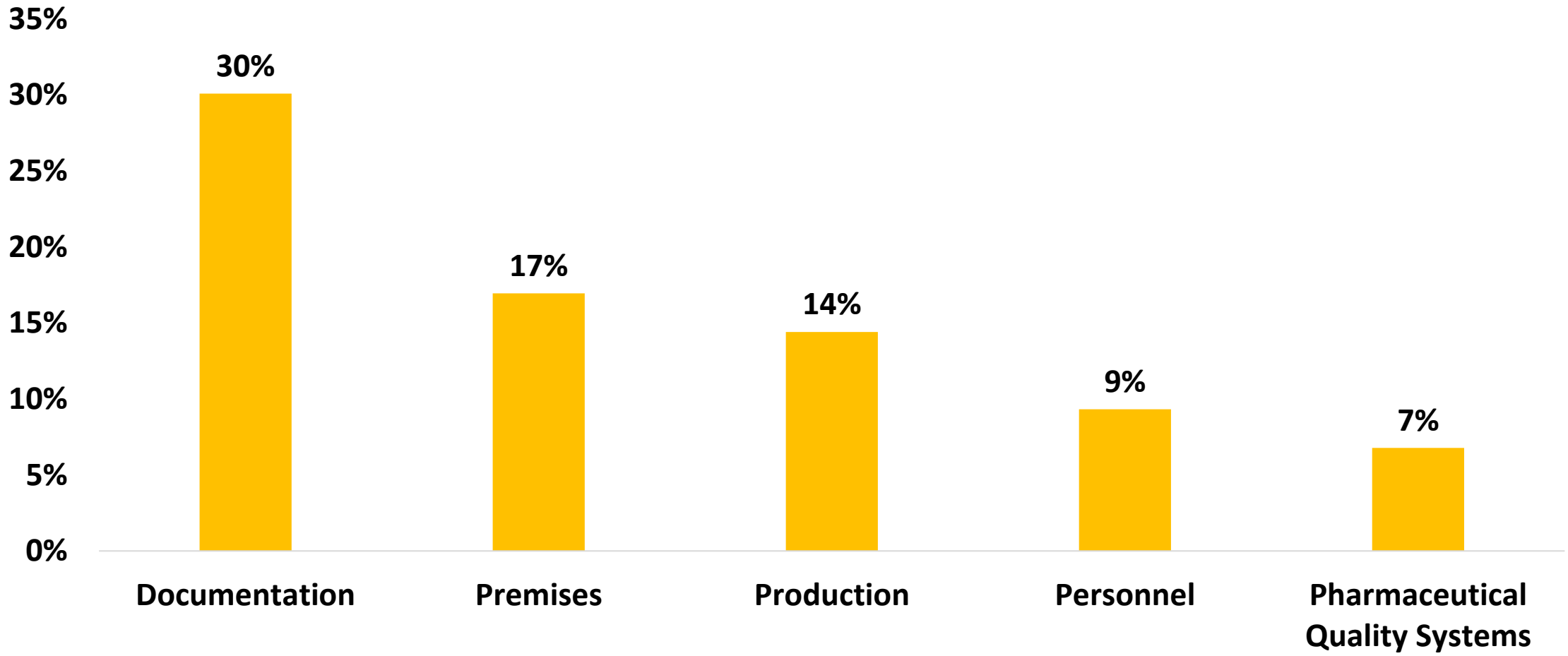
Top 5 GMP Deficiency Categories for Packagers of Chinese Proprietary Medicines in 2025



Top 5 GMP Deficiency Categories for Manufacturers of Active Ingredients in 2025



Top 5 GMP Deficiency Categories for Manufacturers of Cell, Tissue and Gene Therapy Products in 2025



Ranking of Deficiency Categories for Therapeutic Products Manufacturers (2023 to 2025)

Rank	Deficiency Category		
	2023	2024	2025
1	Pharmaceutical Quality Systems	Pharmaceutical Quality Systems	Premises and Equipment
2	Documentation	Premises and Equipment	Documentation
3	Premises and Equipment	Documentation	Pharmaceutical Quality Systems
4	Production	Production	Production
5	Quality Control	Quality Control	Quality Control

Ranking of Deficiency Categories for Chinese Proprietary Medicines Manufacturers (2023 to 2025)

Rank	Deficiency Category		
	2023	2024	2025
1	Documentation	Documentation	Documentation
2	Premises and Equipment	Premises and Equipment	Production
3	Qualification and Validation	Pharmaceutical Quality Systems	Premises and Equipment
4	Production	Production	Pharmaceutical Quality Systems
5	Pharmaceutical Quality Systems	Quality Control	Quality Control

Ranking of Deficiency Categories for Active Ingredients Manufacturers (2023 to 2025)

Rank	Deficiency Category		
	2023	2024	2025
1	Building and Facilities	Building and Facilities	Materials Management
2	Process Equipment	Process Equipment	Process Equipment
3	Documentation and Records	Quality Management	Personnel
4	Validation	Documentation and Records	Quality Management
5	-*	Materials Management	Production and In-process Controls

*Note: All deficiencies fell within 4 categories.

Ranking of Deficiency Categories for Cell, Tissue and Gene Therapy Products Manufacturers (2023 to 2025)

Rank	Deficiency Category		
	2023	2024	2025
1	Documentation	Documentation	Documentation
2	Production	Production	Premises
3	Premises	Personnel	Production
4	Batch Release	Pharmaceutical Quality Systems	Personnel
5	Control of Materials	Control of Materials	Pharmaceutical Quality Systems

Common Deficiencies from Inspections Conducted

Deficiency Category	Example of Deficiencies
Documentation	▪ Documentation control practices and record-keeping were inadequate, with missing signatures on material transfer records, incomplete "checked by" documentation, use of obsolete forms, and inaccurate facility layout descriptions that did not reflect actual operations. ▪ Documentation practices were deficient with inadequate retention of testing data, failure to ensure contemporaneous recording, inaccurate equipment records, and poor document version control. ▪ Poor documentation practices that compromise traceability, including failure to document QC's assessment of the growth promotion test results of culture media, incomplete cleaning records (cleaning of BSC glass sash not documented) and inadequate viral vector traceability records (key information such as receipt dates and storage locations was lacking).
Material Management	▪ Temperature monitoring was not routinely conducted for multiple storage units including refrigerators, freezers, and cryogenic tanks. ▪ Documentation was not maintained to identify the personnel who conducted the re-labelling of materials and the date and time when these activities occurred. ▪ The identity numbers of flexible solvent transfer hoses were completely obscured by colour-coded tapes, which prevented verification of hose identity before transferring bulk solvents from tanker to solvent tank as required, and posed potential risks of mix-ups of the hoses.

Common Deficiencies from Inspections Conducted

Deficiency Category	Example of Deficiencies
Pharmaceutical Quality Systems	▪ Change control procedures were not implemented for several significant changes with GMP impact, e.g., change of supplier for 200ml plastic bottles used in primary packaging, change of pest control vendor. ▪ Quality risk management documentation was inadequate, e.g., clear justification for differential environmental monitoring approaches lacking, gap assessment with risk ranking without a risk scoring matrix reference. ▪ Investigation of deviations not properly carried out, e.g., multiple cleanroom environmental monitoring failures not followed with timely investigation, insufficient root cause analysis that lacked supporting evidence, no evaluation of effectiveness of corrective measures.
Quality Control	▪ Microbial testing of the liquid product was performed before primary packaging but was not conducted after completion of the bottling process. ▪ The purified water system sampling program did not include regular chemical and microbial water quality monitoring of all points of use and exclusion of certain sampling points without proper justification. ▪ Poor QC laboratory practices which potentially compromised the accuracy and reliability of test results, e.g., reagent solutions and stock solutions without defined in-use shell life were used without assessment of continued suitability, use of solutions that showed signs of degradation.

Common Deficiencies from Inspections Conducted

Deficiency Category	Example of Deficiencies
Premises and Equipment	▪ The pest control program was ineffective as evidenced by the presence of cobwebs, insects, and pests that were observed in multiple storage and production areas, along with faulty pest control equipment. ▪ Poor equipment and premises labelling practices, e.g., missing status indicators for production rooms and equipment, unlabeled sampling points, missing stainless steel container and sieves identification. ▪ Routine temperature monitoring of warehouse areas did not include all identified hot spots from the temperature mapping study.
Production and In-Process Control	▪ Manufacturing processes for preparation, quality control and storage of critical solutions and materials were not adequately defined in written procedures or batch manufacturing records which compromised process control and assurance of material quality and traceability, e.g., missing documentation of preparation steps, inadequate storage practices, undefined material shelf life. ▪ The aseptic process simulation study did not provide adequate sterility assurance, e.g., actual cell culture media was used instead of general-purpose non-selective culture medium, critical aseptic processing steps not covered, no consideration of worst-case scenarios. ▪ Visual inspection of finished CTGT product was inadequate, e.g., inspection results not documented in batch processing records, lack of regular eyesight check requirements for personnel performing the inspection, controlled illumination conditions of inspection stations not defined.

Common Deficiencies from Inspections Conducted

Deficiency Category	Example of Deficiencies
Personnel	▪ An operator in the Grade C fermentation room was observed picking up used isopropyl alcohol wipes from the floor and resumed work without disinfecting the gloved hands or changing to new gloves. This posed potential contamination risks to the processes and products. ▪ Personnel training and procedural guidance were inadequate, e.g., SOP for Aseptic Technique and On-the-Job training document did not provide instructions for sterile glove replacement, handling of situations when glove integrity was compromised (torn gloves), major spillages during aseptic operations. ▪ Personnel gowning procedures were inadequate, e.g., lack of requirements for changeover of personnel production attire for transitioning between areas of different cleanliness classification, street sock removal and clean sock donning.



Audit and Licensing Division | Health Products Regulation Group
Email: hsa_gmp@hsa.gov.sg