



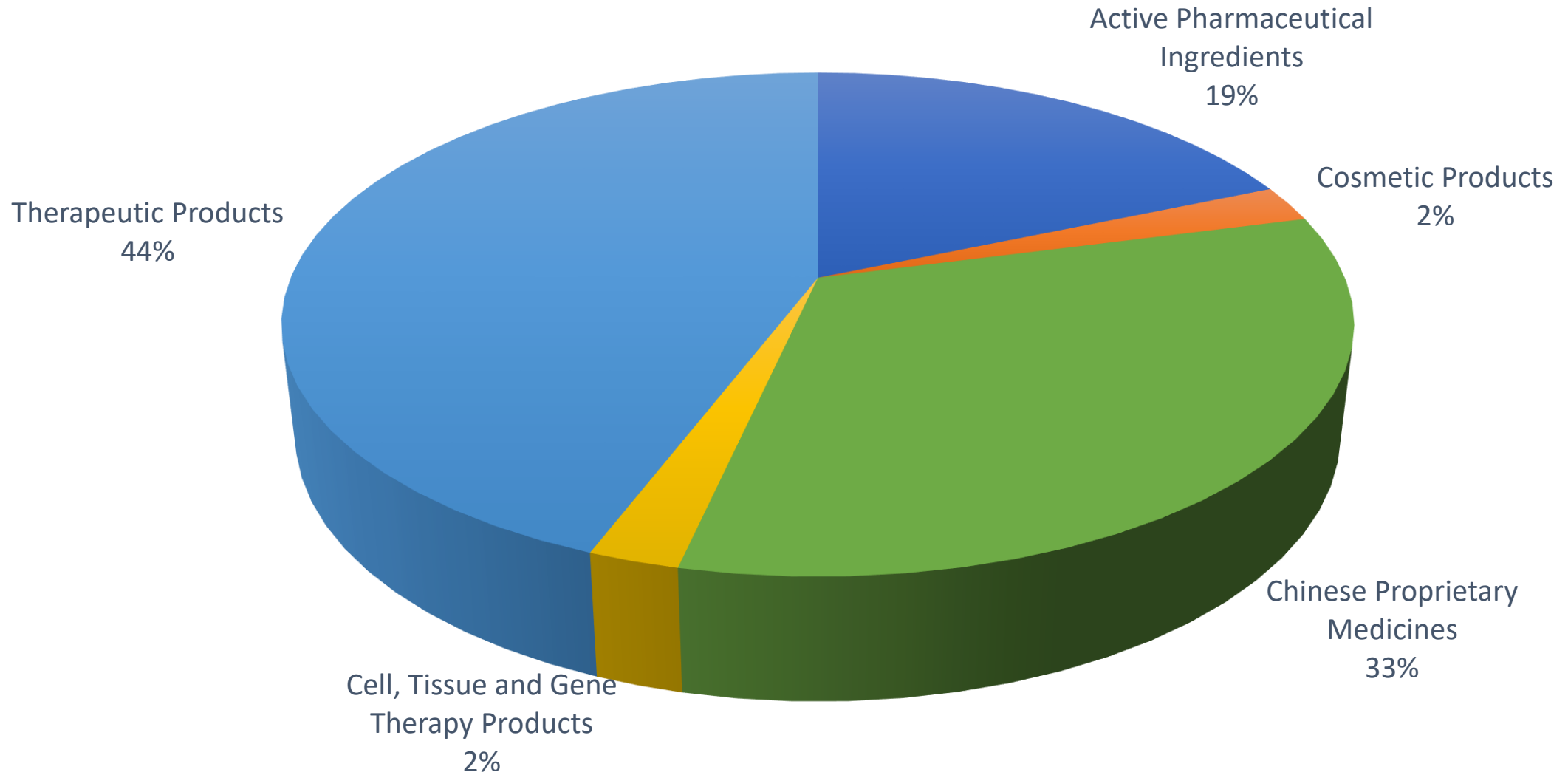
Trending of GMP Deficiencies of Manufacturers For Year 2022

By Good Manufacturing Practice Unit

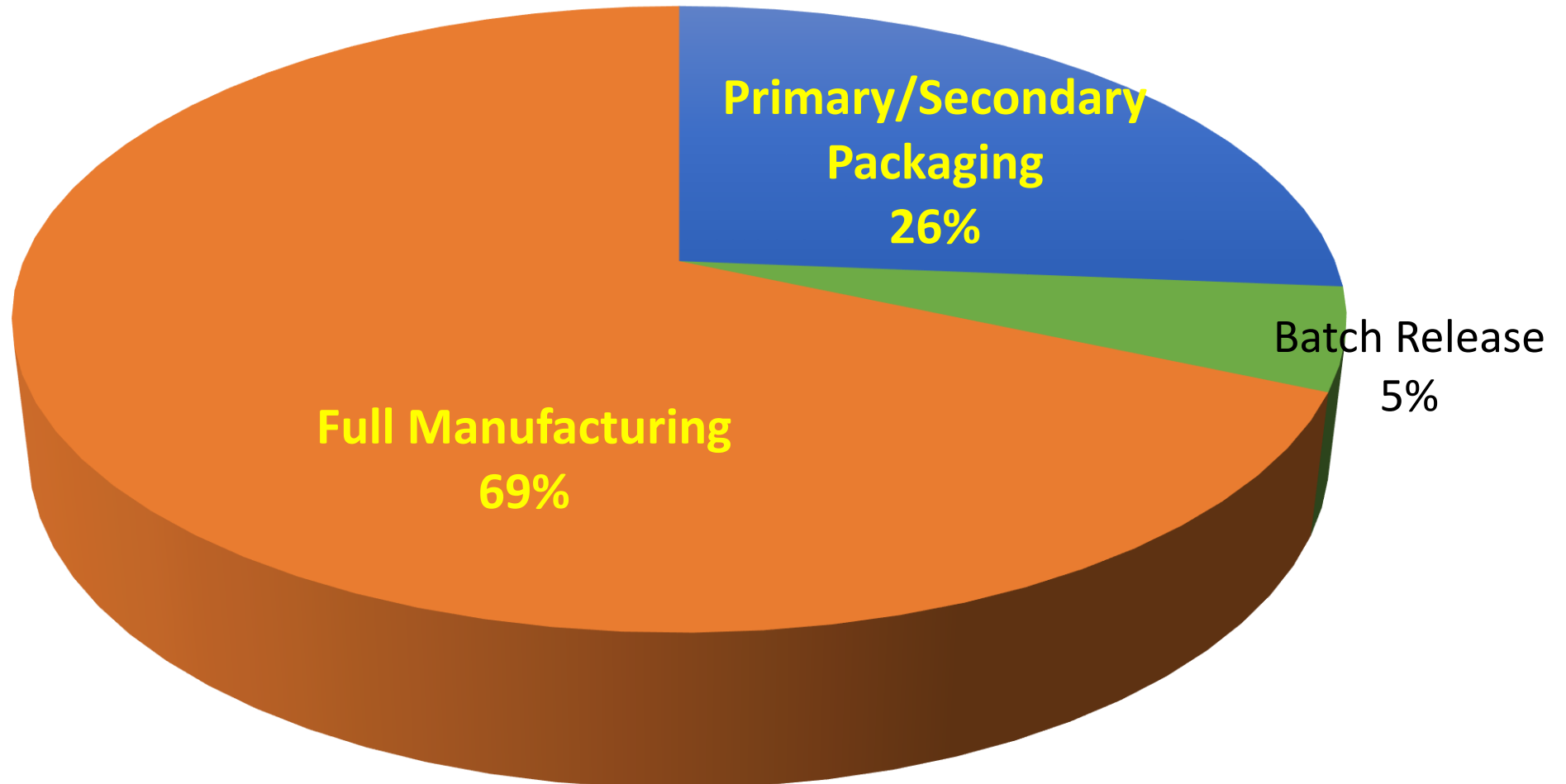
Audit and Licensing Division | Health Products Regulation Group

Email: hsa_gmp@hsa.gov.sg

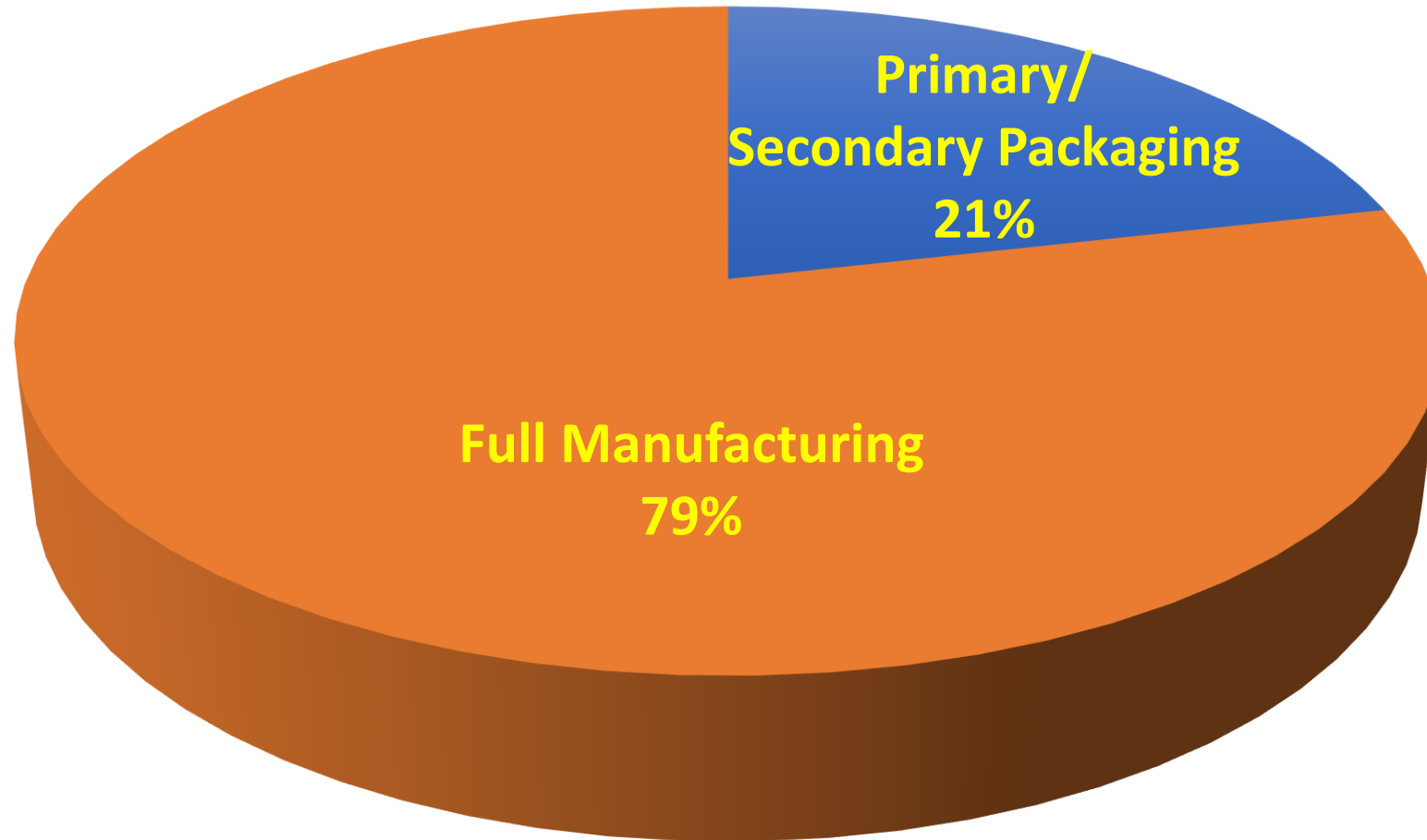
Profiles of Manufacturers Inspected in Year 2022



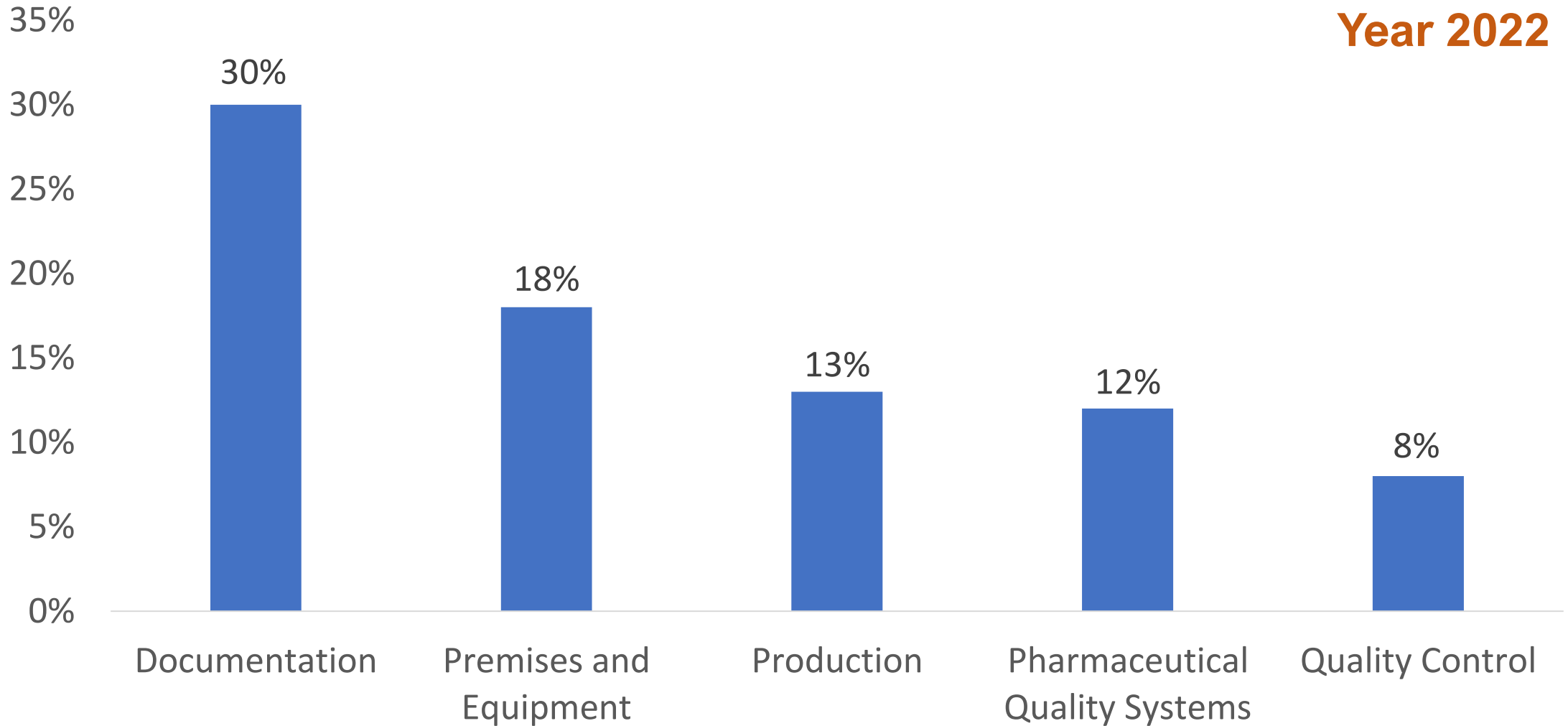
Therapeutic Products Manufacturers Inspected in 2022



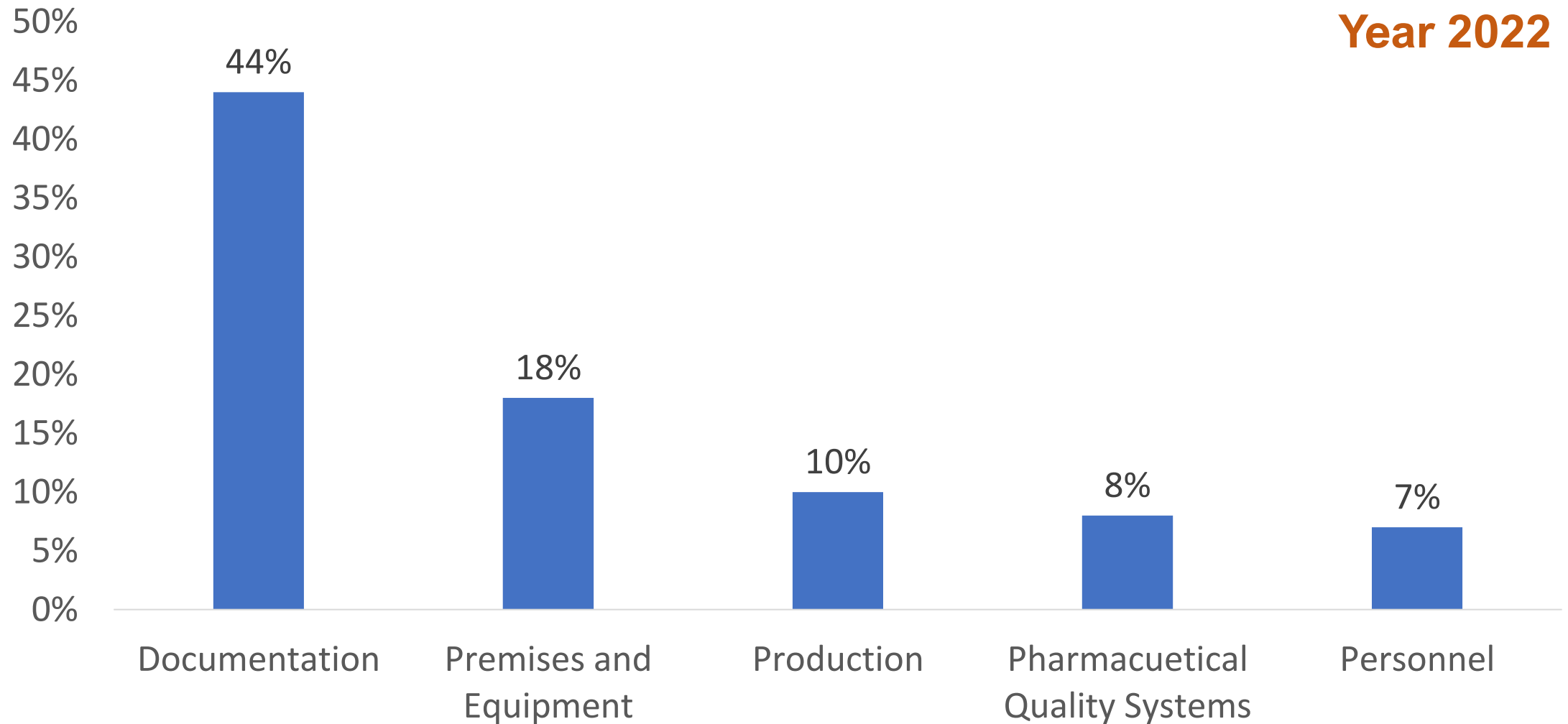
Chinese Proprietary Medicine Manufacturers Inspected in 2022



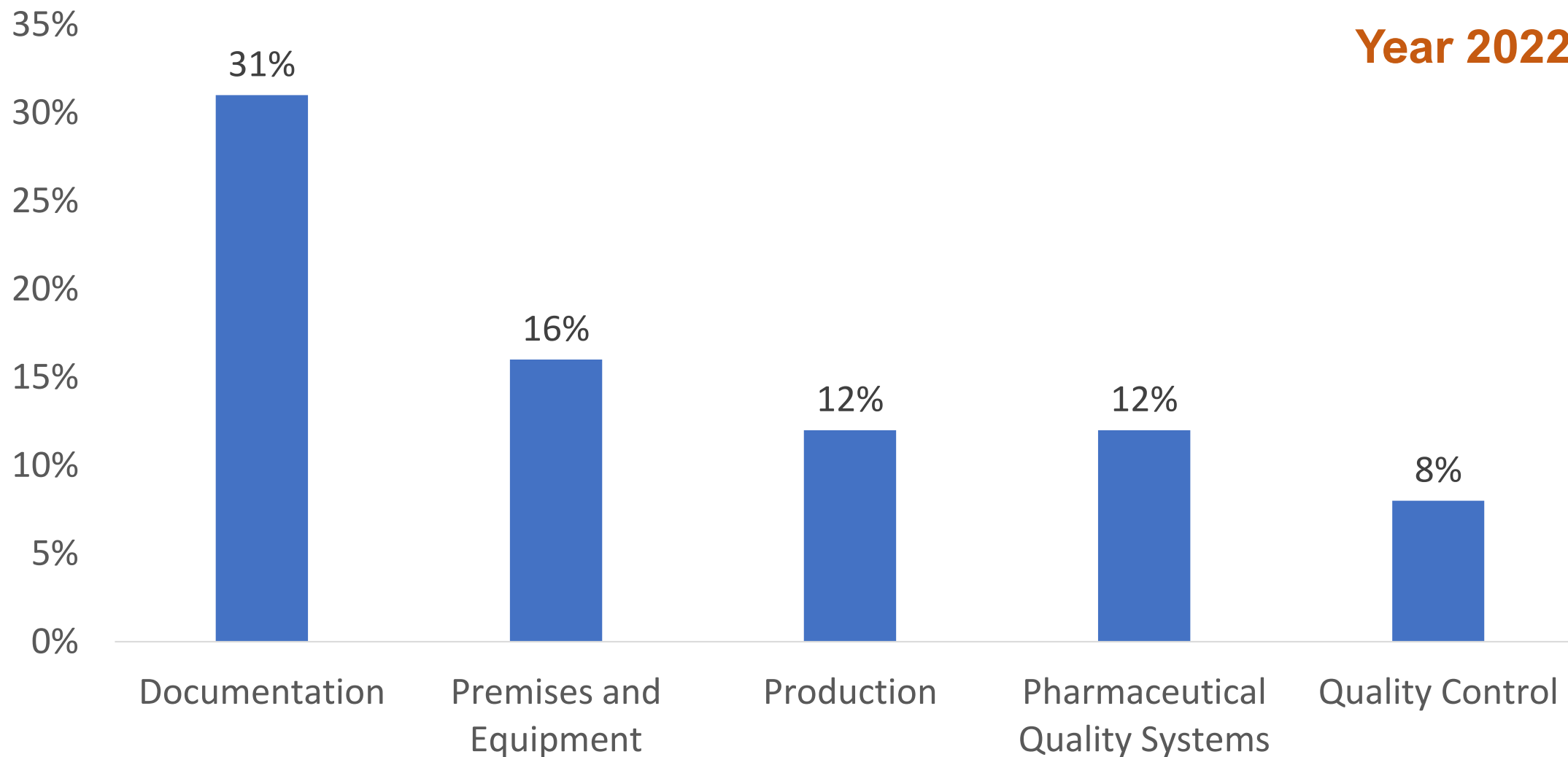
Top 5 GMP Deficiencies for Pharmaceutical Finished Product Full Manufacturers



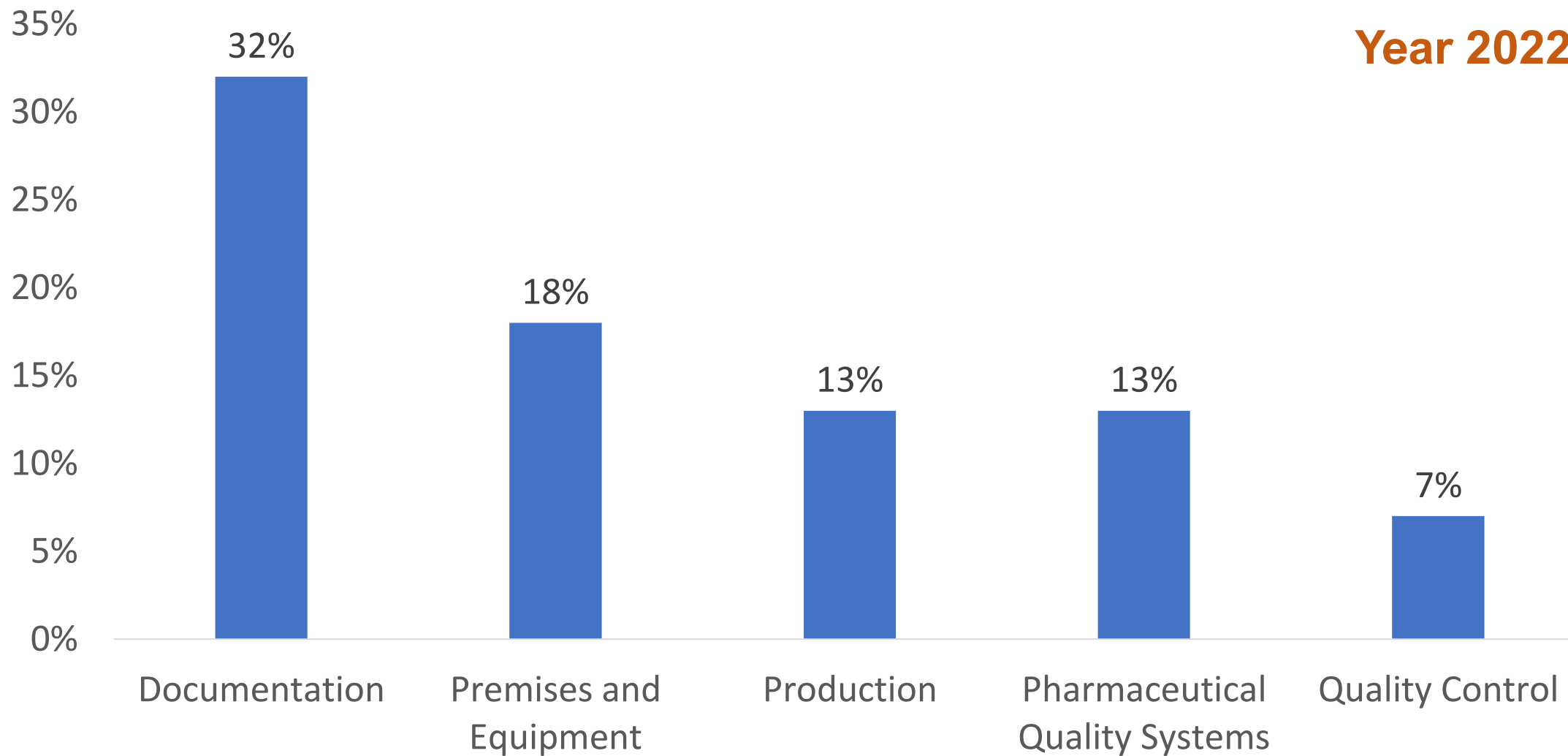
Top 5 GMP Deficiencies for Pharmaceutical Finished Product Packagers



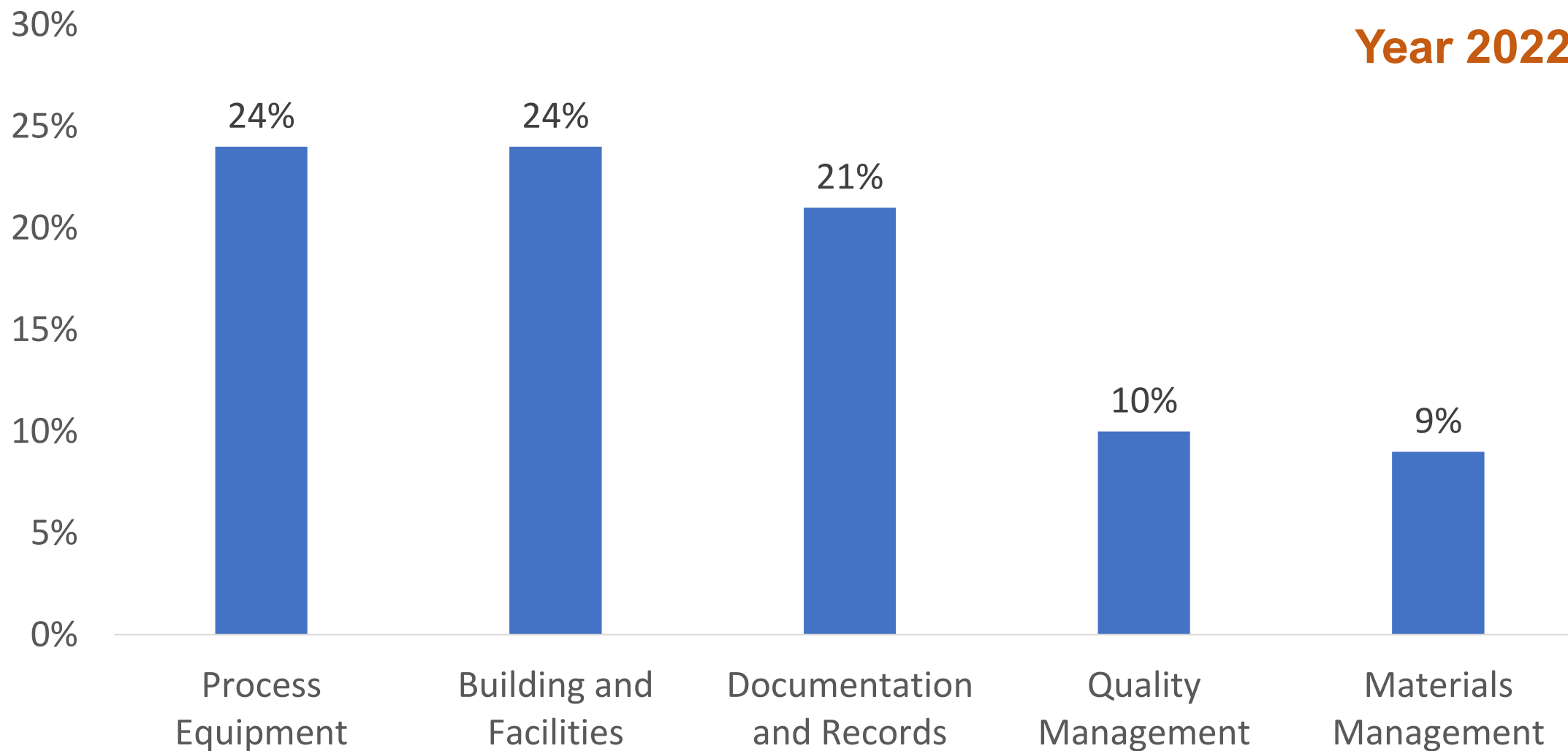
Top 5 GMP Deficiencies for Manufacturers of Therapeutic Products



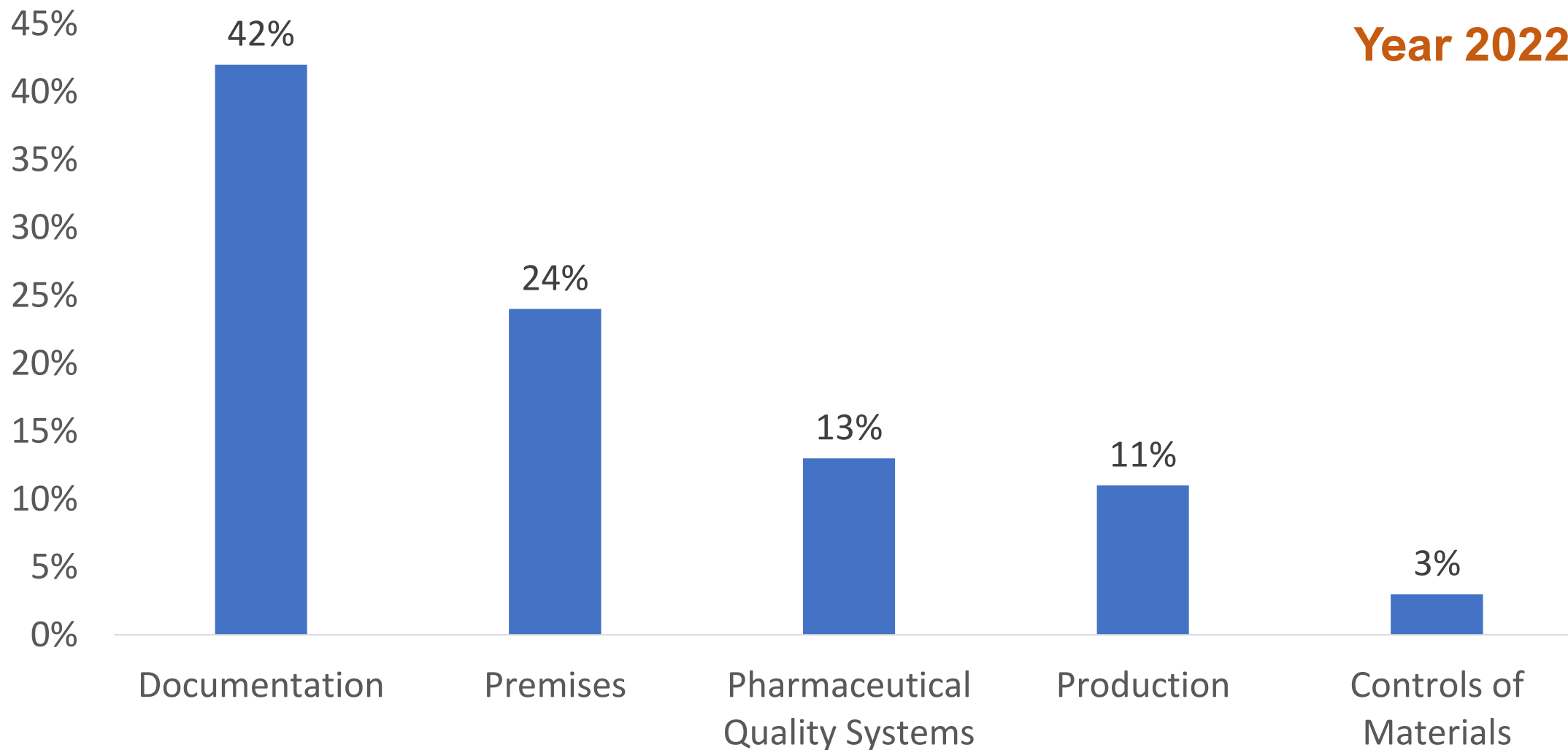
Top 5 GMP Deficiencies for Manufacturers of Chinese Proprietary Medicines



Top 5 GMP Deficiencies for Manufacturers of Active Pharmaceutical Ingredients



Top 5 GMP Deficiencies for Manufacturers of Cell, Tissue and Gene Therapy Products



Ranking of Deficiencies for Therapeutic Products Manufacturers (2020 to 2022)

Rank	Category of Deficiencies		
	2020	2021	2022
1	Documentation	Documentation	Documentation
2	Pharmaceutical Quality Systems	Premises and Equipment	Premises and Equipment
3	Production	Production	Production
4	Premises and Equipment	Pharmaceutical Quality Systems	Pharmaceutical Quality Systems
5	Qualification and Validation	Quality Control	Quality Control

Ranking of Deficiencies for Chinese Proprietary Medicines Manufacturers (2020 to 2022)

Rank	Category of Deficiencies		
	2020	2021	2022
1	Documentation	Documentation	Documentation
2	Production	Premises and Equipment	Premises and Equipment
3	Qualification and Validation	Production	Production
4	Premises and Equipment	Pharmaceutical Quality Systems	Pharmaceutical Quality Systems
5	Pharmaceutical Quality Systems	Quality Control	Quality Control

Ranking of Deficiencies for Active Pharmaceutical Ingredients Manufacturers (2020 to 2022)

Rank	Category of Deficiencies		
	2020	2021	2022
1	Quality Management	Documentation and Records	Building and Facilities
2	Documentation and Records	Building and Facilities	Process Equipment
3	Process Equipment	Process Equipment	Documentation and Records
4	Materials Management	Quality Management	Quality Management
5	Building and Facilities	Materials Management	Materials Management