

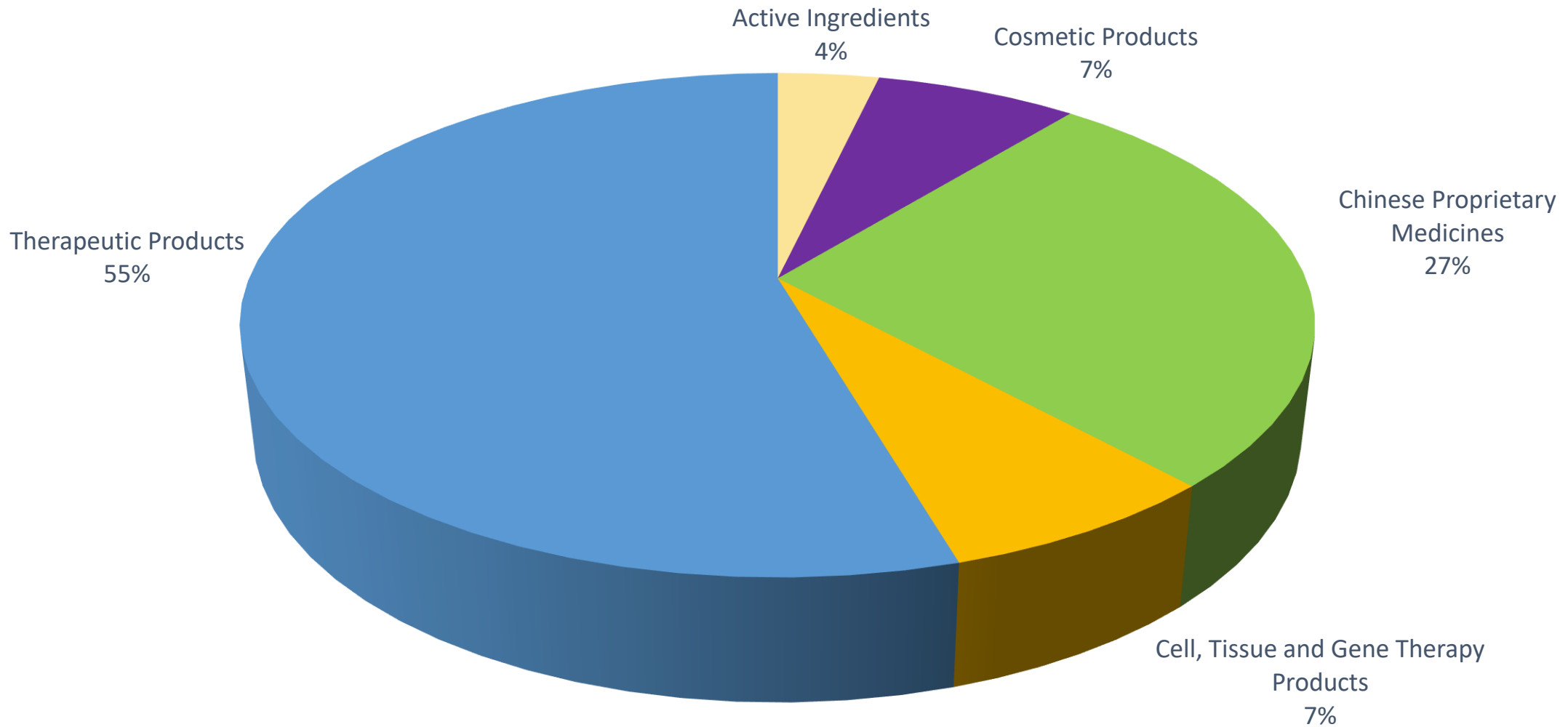
# Trending of GMP Deficiencies of Manufacturers For Year 2023

By Good Manufacturing Practice Unit

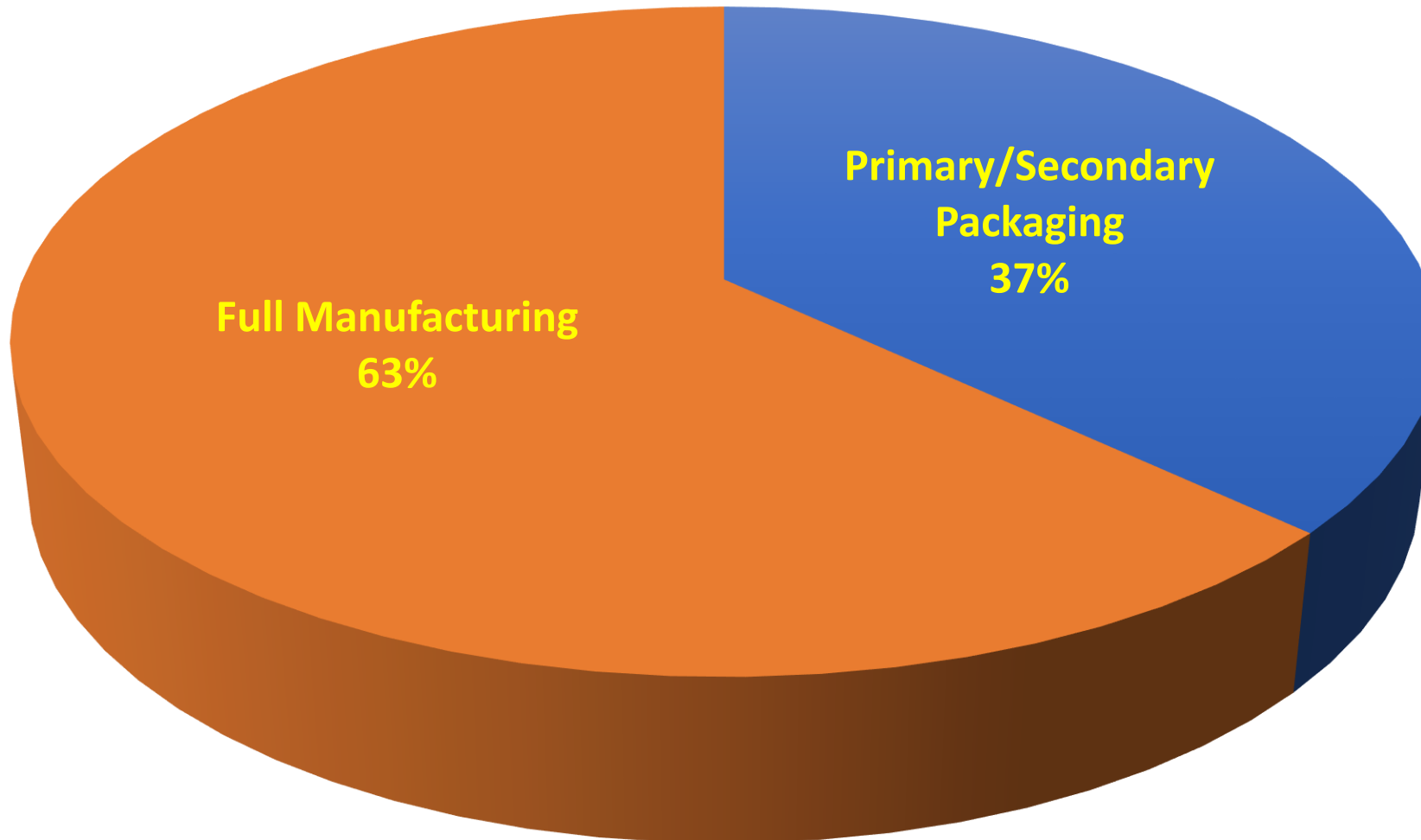
Audit and Licensing Division | Health Products Regulation Group

Email: [hsa\\_gmp@hsa.gov.sg](mailto:hsa_gmp@hsa.gov.sg)

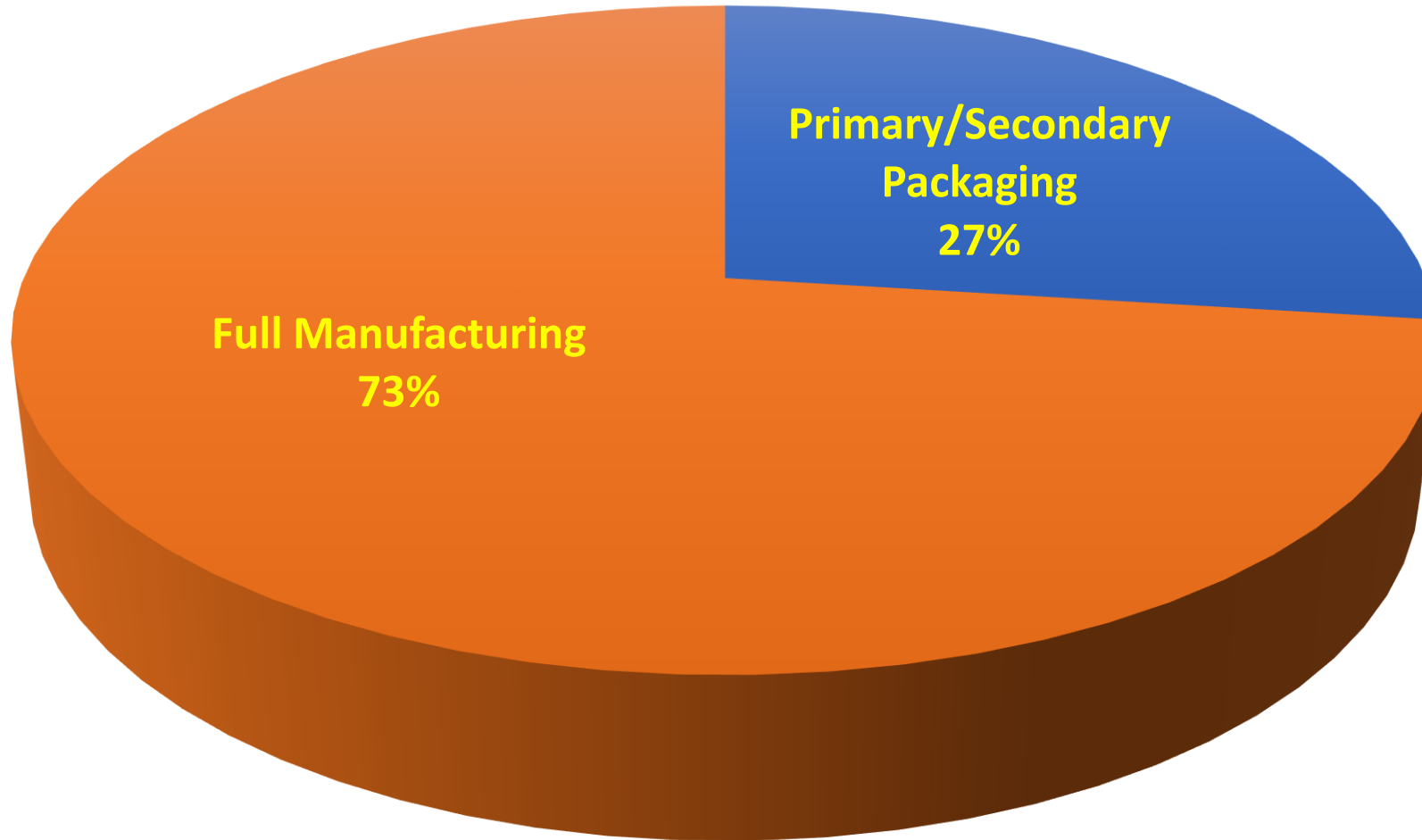
# Profile of Manufacturers for Inspection Conducted in Year 2023



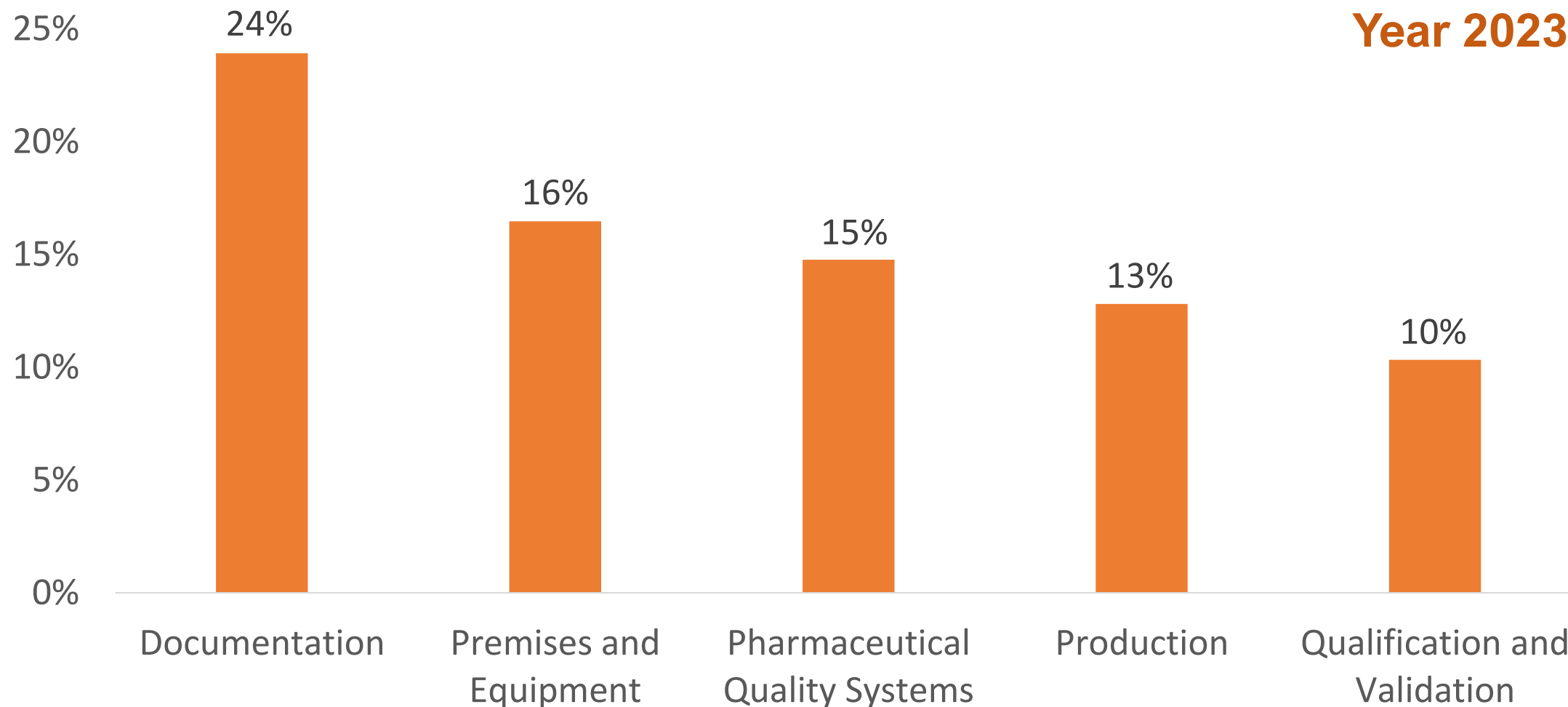
# Therapeutic Products Manufacturers Inspected in 2023



# Chinese Proprietary Medicine Manufacturers Inspected in 2023

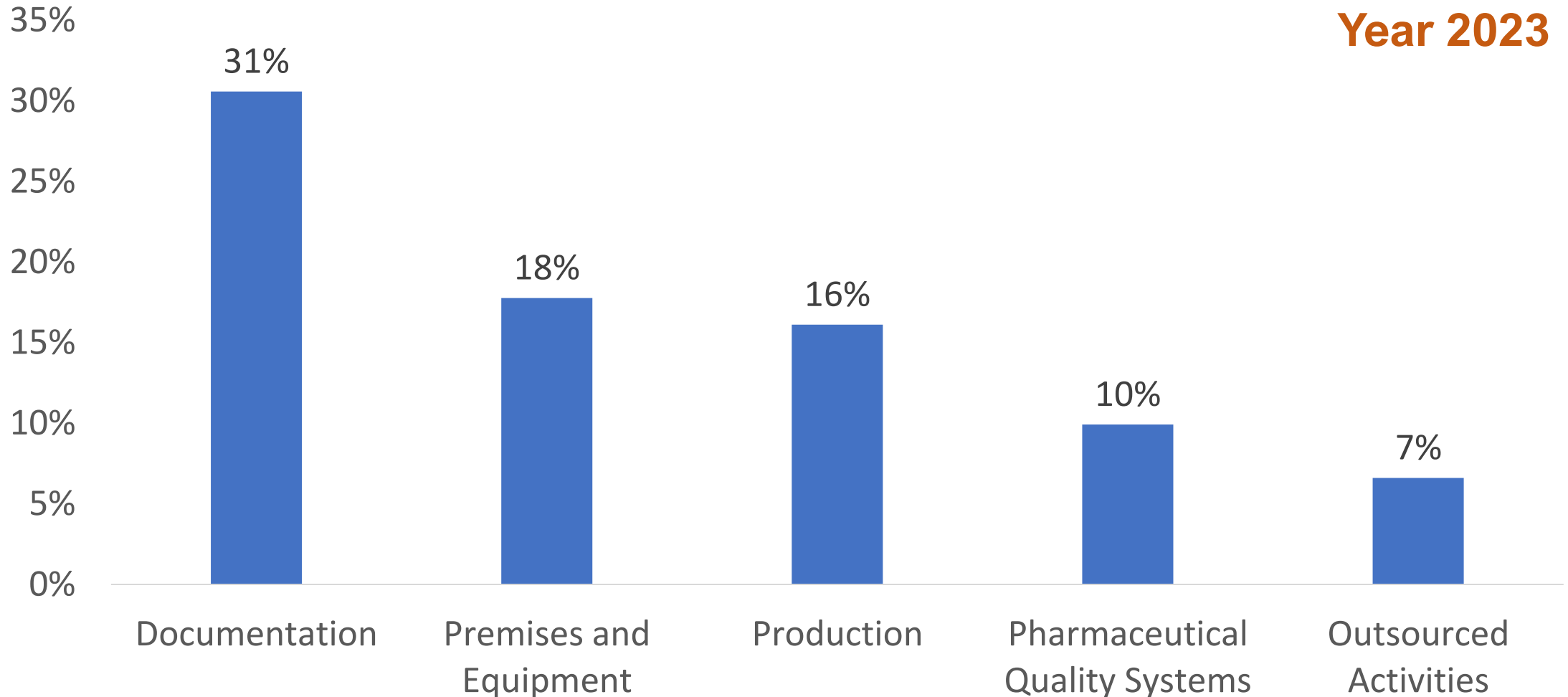


# Top 5 GMP Deficiencies for Pharmaceutical Finished Product\* Full Manufacturers



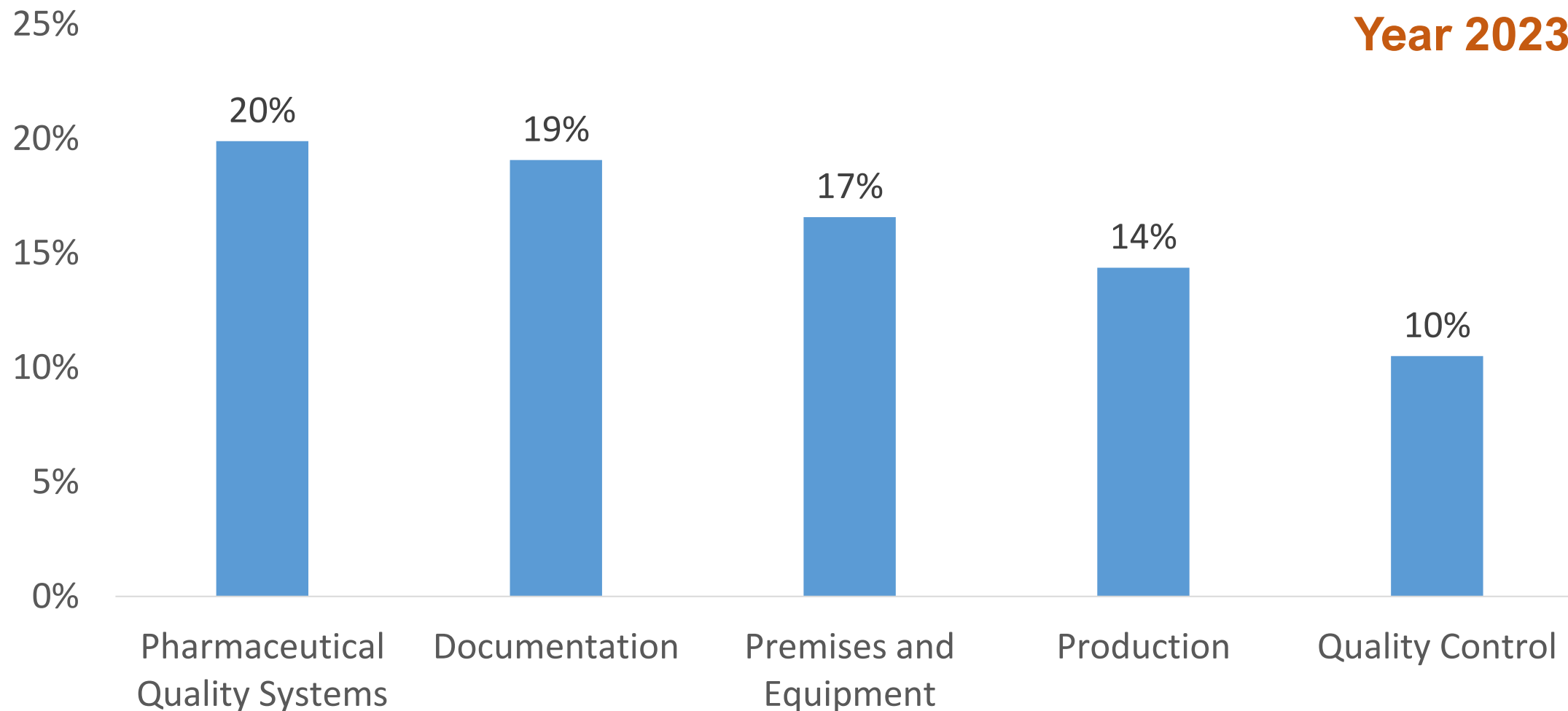
\* Finished product includes Therapeutic Products and Chinese Proprietary Medicines

# Top 5 GMP Deficiencies for Pharmaceutical Finished Product\* Packagers

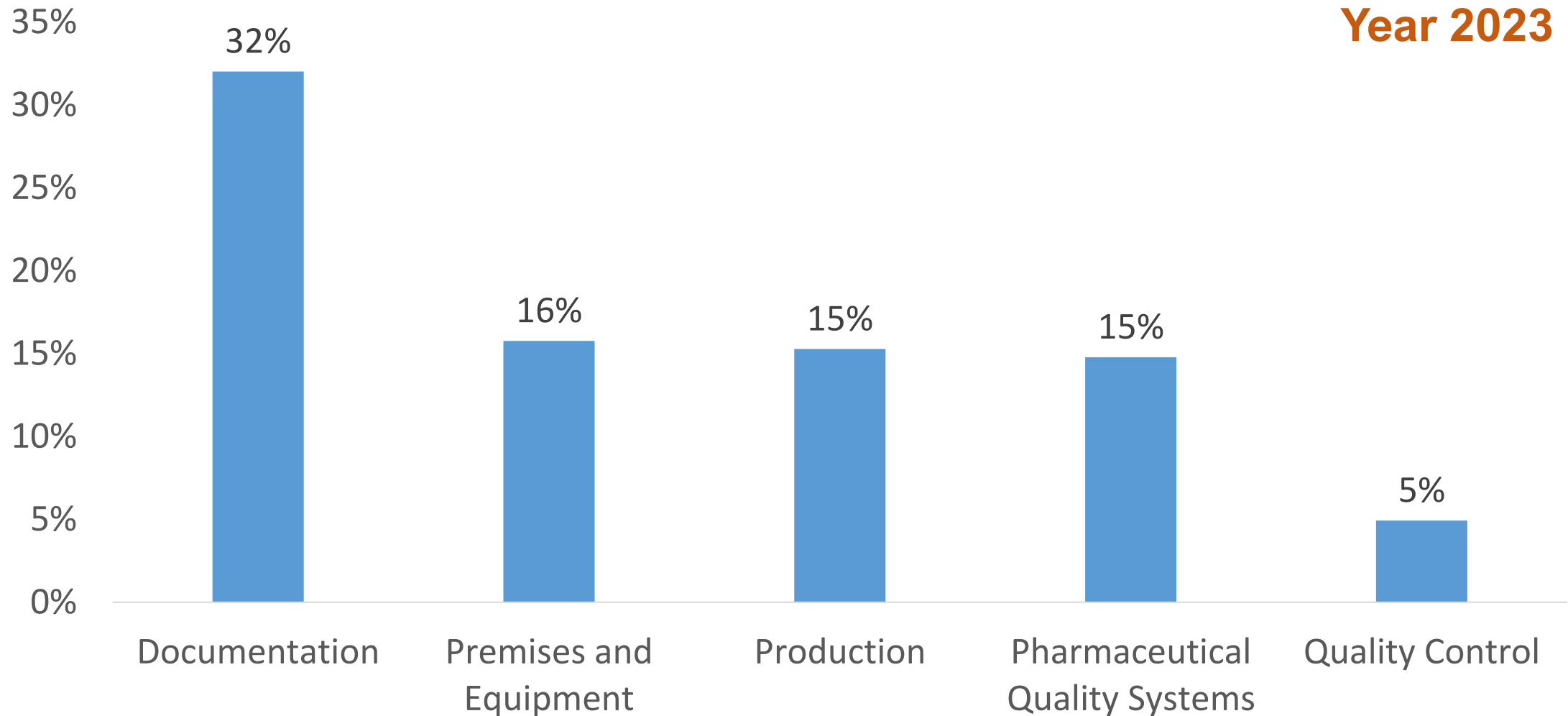


\* Finished product includes Therapeutic Products and Chinese Proprietary Medicines

# Top 5 GMP Deficiencies for Full Manufacturers of Therapeutic Products

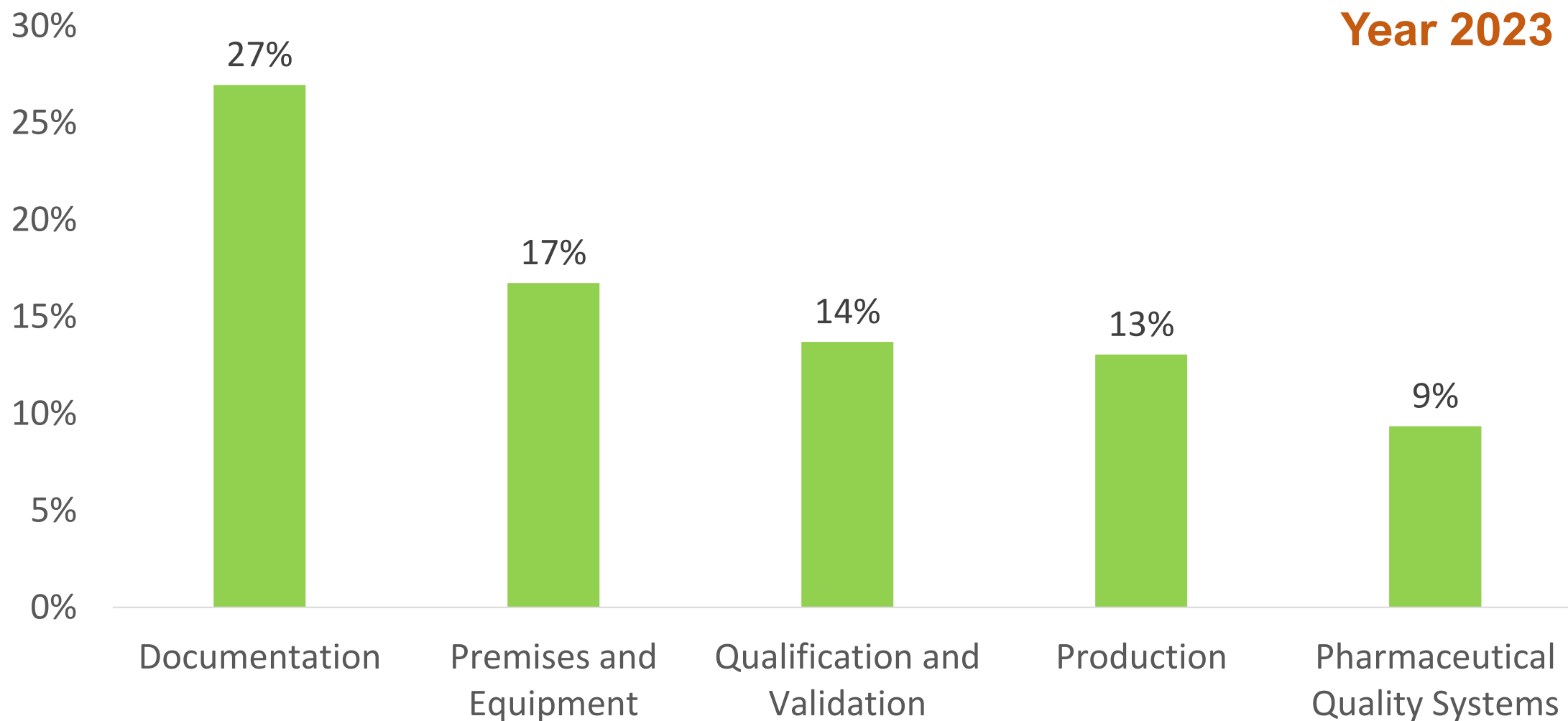


# Top 5 GMP Deficiencies for Packagers of Therapeutic Products

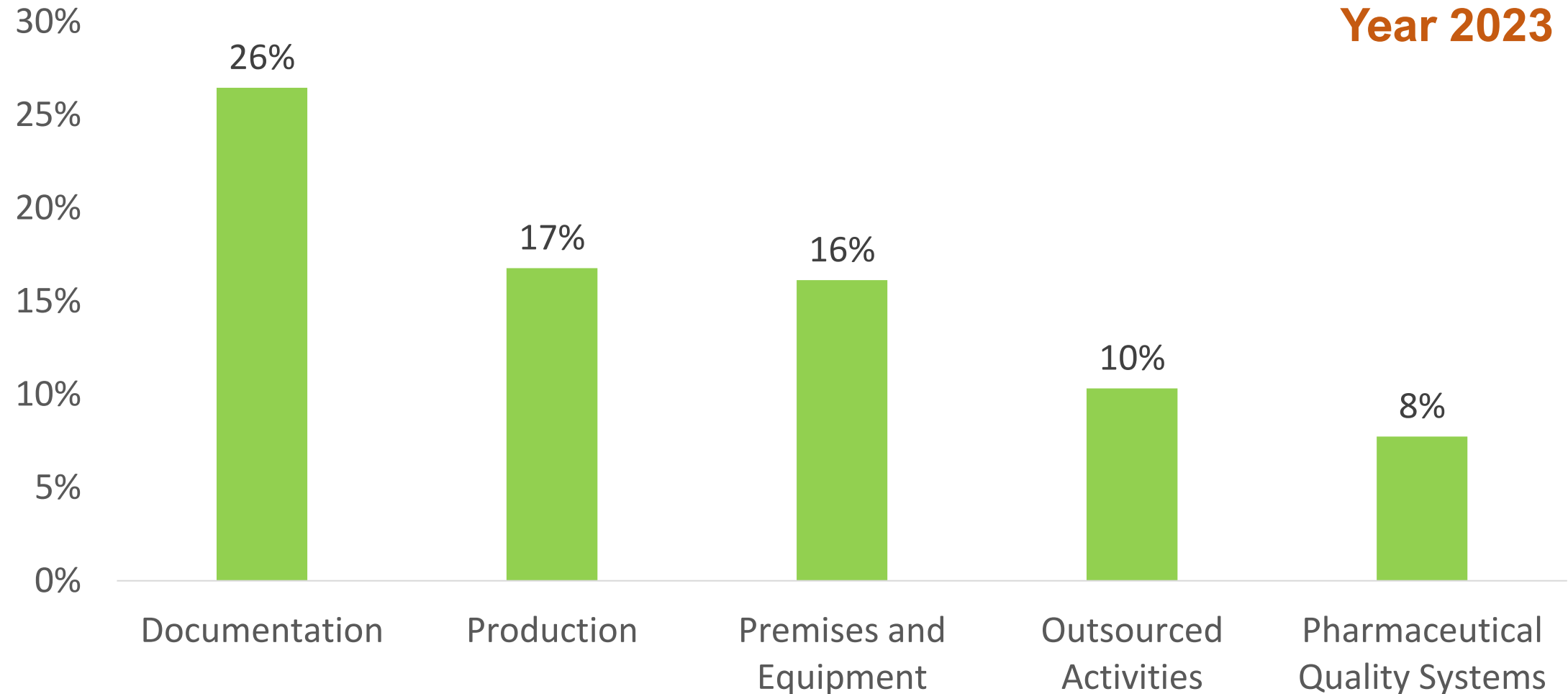




# Top 5 GMP Deficiencies for Full Manufacturers of Chinese Proprietary Medicines

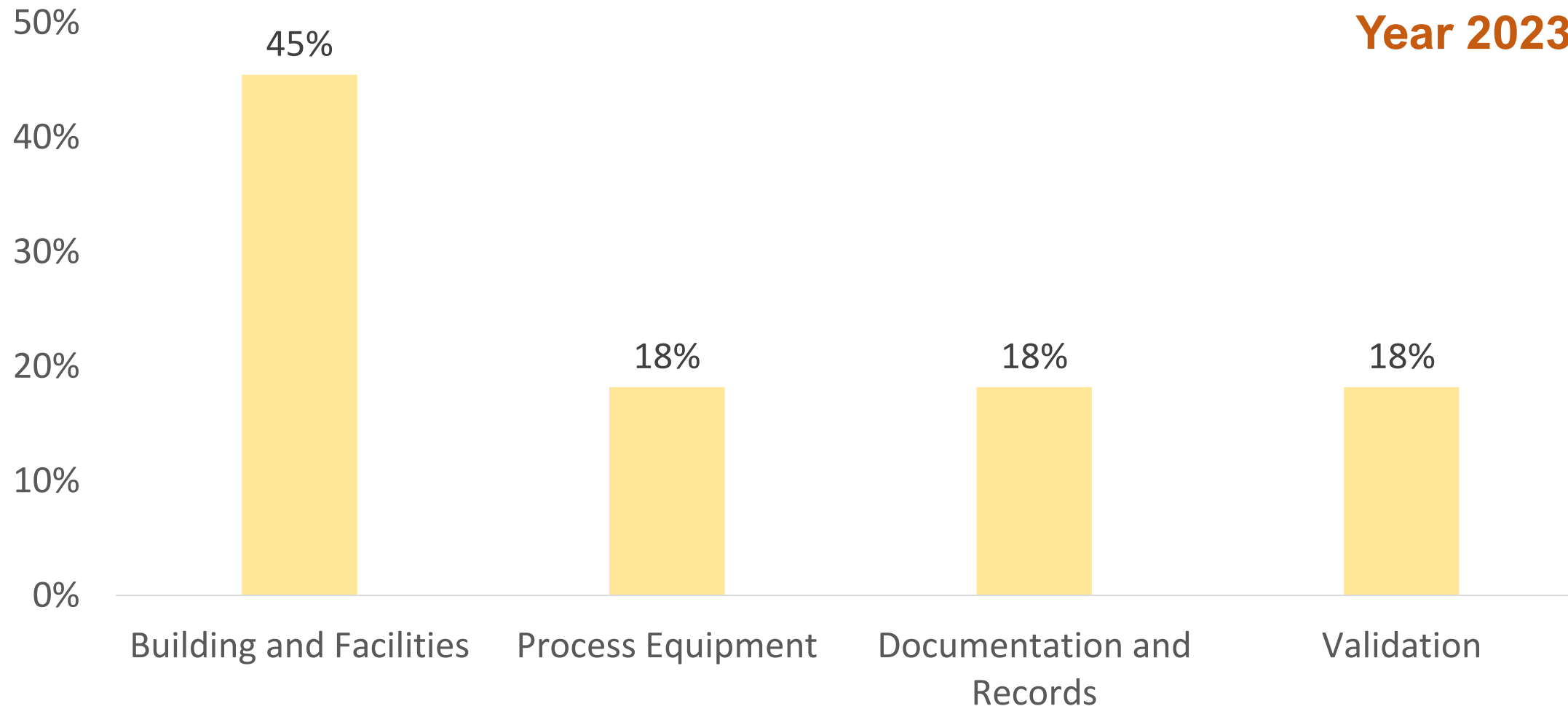


# Top 5 GMP Deficiencies for Packagers of Chinese Proprietary Medicines



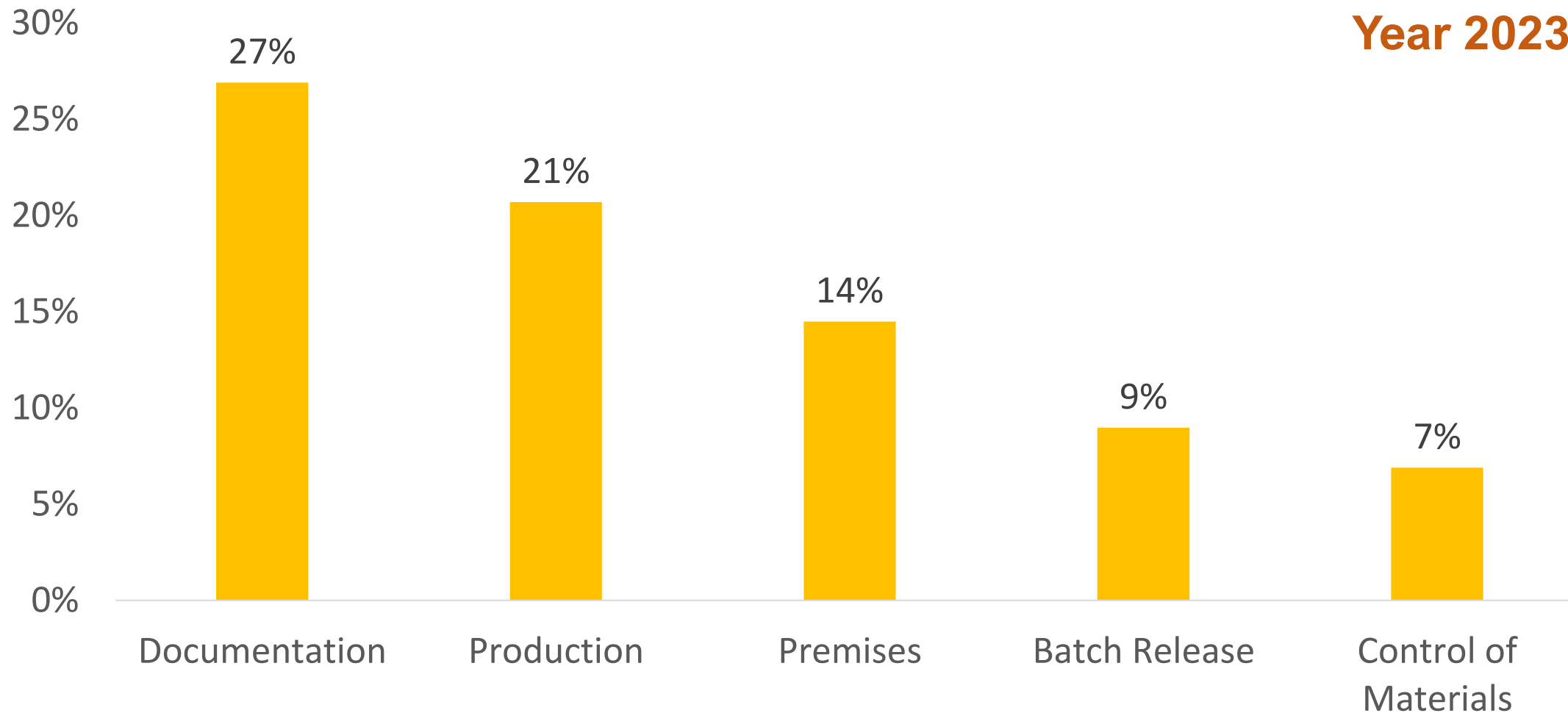


# Top 5\* GMP Deficiencies for Manufacturers of Active Ingredients



\*Note: All deficiencies fell within 4 categories.

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



# Ranking of Deficiencies for Therapeutic Products Manufacturers (2021 to 2023)

Rank	Category of Deficiencies		
	2021	2022	2023
1	Documentation	Documentation	Pharmaceutical Quality Systems
2	Premises and Equipment	Premises and Equipment	Documentation
3	Production	Production	Premises and Equipment
4	Pharmaceutical Quality Systems	Pharmaceutical Quality Systems	Production
5	Quality Control	Quality Control	Quality Control

# Ranking of Deficiencies for Chinese Proprietary Medicines Manufacturers (2021 to 2023)

Rank	Category of Deficiencies		
	2021	2022	2023
1	Documentation	Documentation	Documentation
2	Premises and Equipment	Premises and Equipment	Premises and Equipment
3	Production	Production	Qualification and Validation
4	Pharmaceutical Quality Systems	Pharmaceutical Quality Systems	Production
5	Quality Control	Quality Control	Pharmaceutical Quality Systems

# Ranking of Deficiencies for Active Ingredients Manufacturers (2021 to 2023)

Rank	Category of Deficiencies		
	2021	2022	2023
1	Documentation and Records	Building and Facilities	Building and Facilities
2	Building and Facilities	Process Equipment	Process Equipment
3	Process Equipment	Documentation and Records	Documentation and Records
4	Quality Management	Quality Management	Validation
5	Materials Management	Materials Management	-*

\*Note: All deficiencies fell within 4 categories.

# Ranking of Deficiencies for Cell, Tissue and Gene Therapy Products Manufacturers (2021 to 2023)

Rank	Category of Deficiencies		
	2021	2022	2023
1	Production	Documentation	Documentation
2	Documentation	Premises	Production
3	Qualification and Validation	Pharmaceutical Quality Systems	Premises
4	Premises	Production	Batch Release
5	Pharmaceutical Quality Systems	Quality Control	Control of Materials