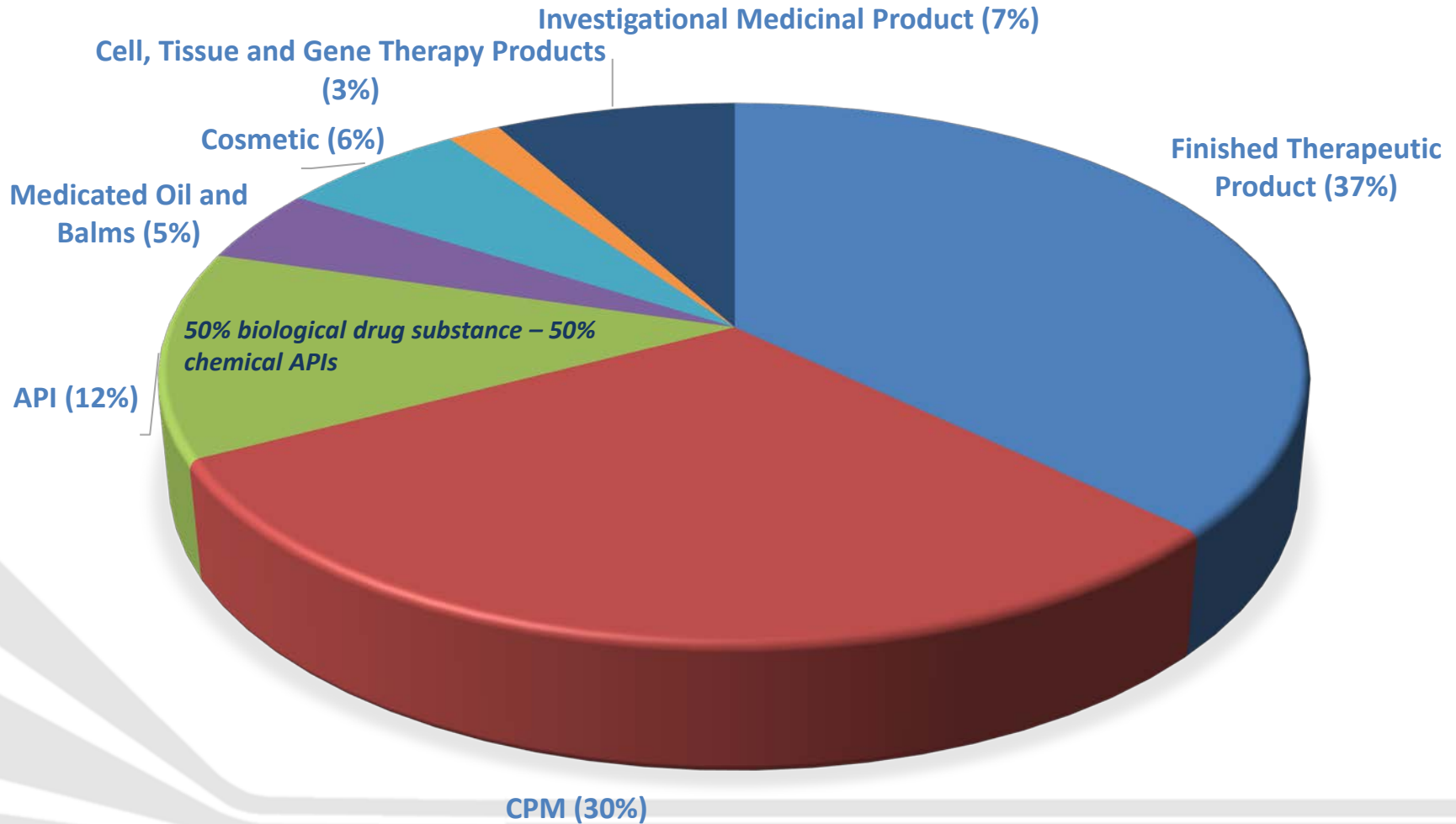


# CLASSIFICATION OF GMP NON-CONFORMITIES

Compilation from all GMP audits of licensed and GMP certified manufacturers conducted in **Year 2019**.

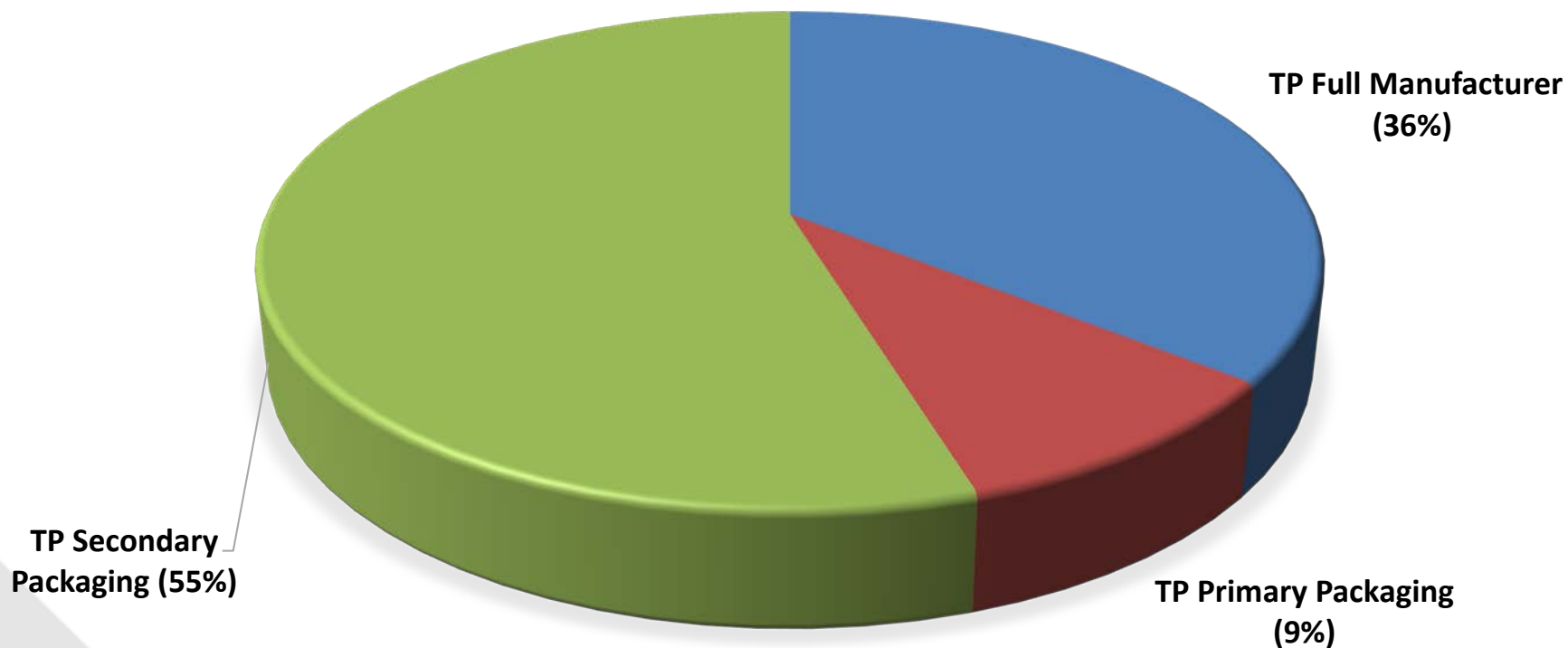
# Manufacturing Landscape in Singapore

## Manufacturers Licensed / Certified by HSA



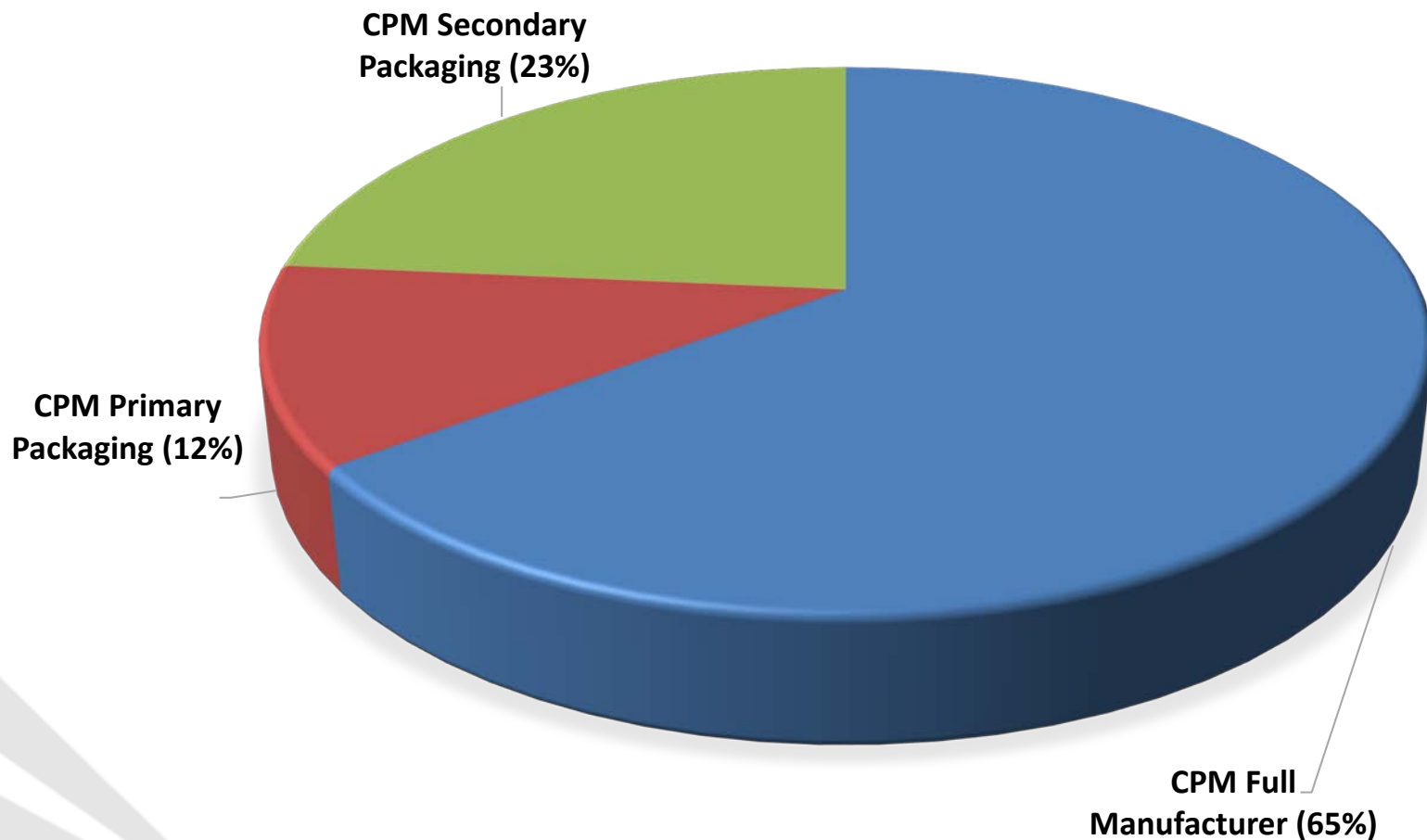
# Manufacturing Landscape in Singapore

## Activities of Therapeutic Products (TP) Manufacturers Licensed by HSA



# Manufacturing Landscape in Singapore

## Activities of Chinese Proprietary Medicines (CPM) Manufacturers Licensed by HSA



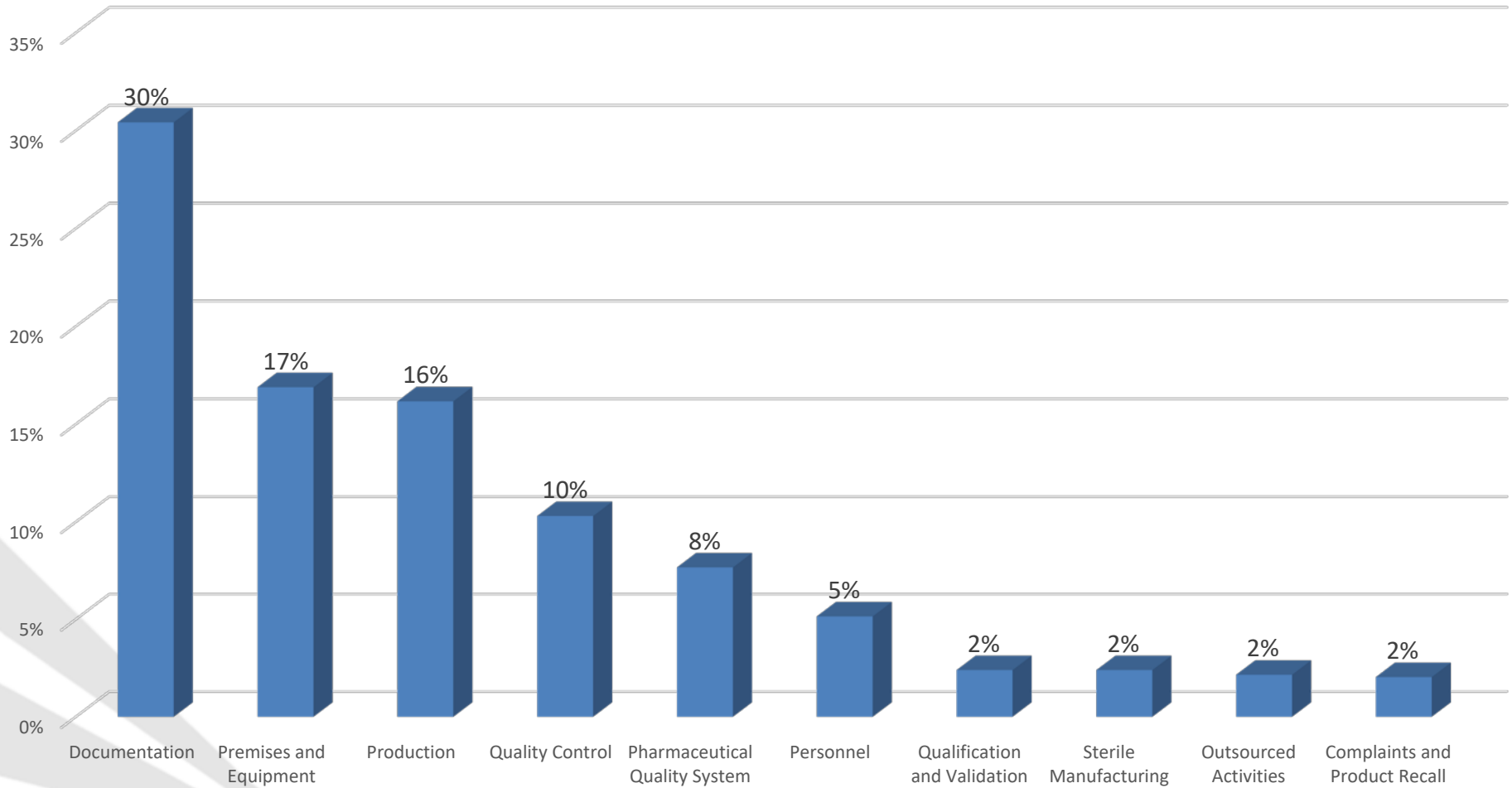
# GMP Inspection Trends

## Top 10 Non-Conformities Raised for all GMP Audits Conducted in 2019

- |   |
|---|
| <b>1. Documentation (including Data Integrity and Management)</b>                               |
| <b>2. Premises and Equipment</b>  |
| <b>3. Production</b>  |
| <b>4. Quality Control</b>   |
| <b>5. Pharmaceutical Quality System<br/>(including management of deviation, change control)</b> |
| <b>6. Personnel (including Training and Competency)</b>   |
| <b>7. Qualification and Validation</b>  |
| <b>8. Sterile Manufacturing</b>   |
| <b>9. Outsourced Activities</b>   |
| <b>10. Complaints and Product Recall</b>  |

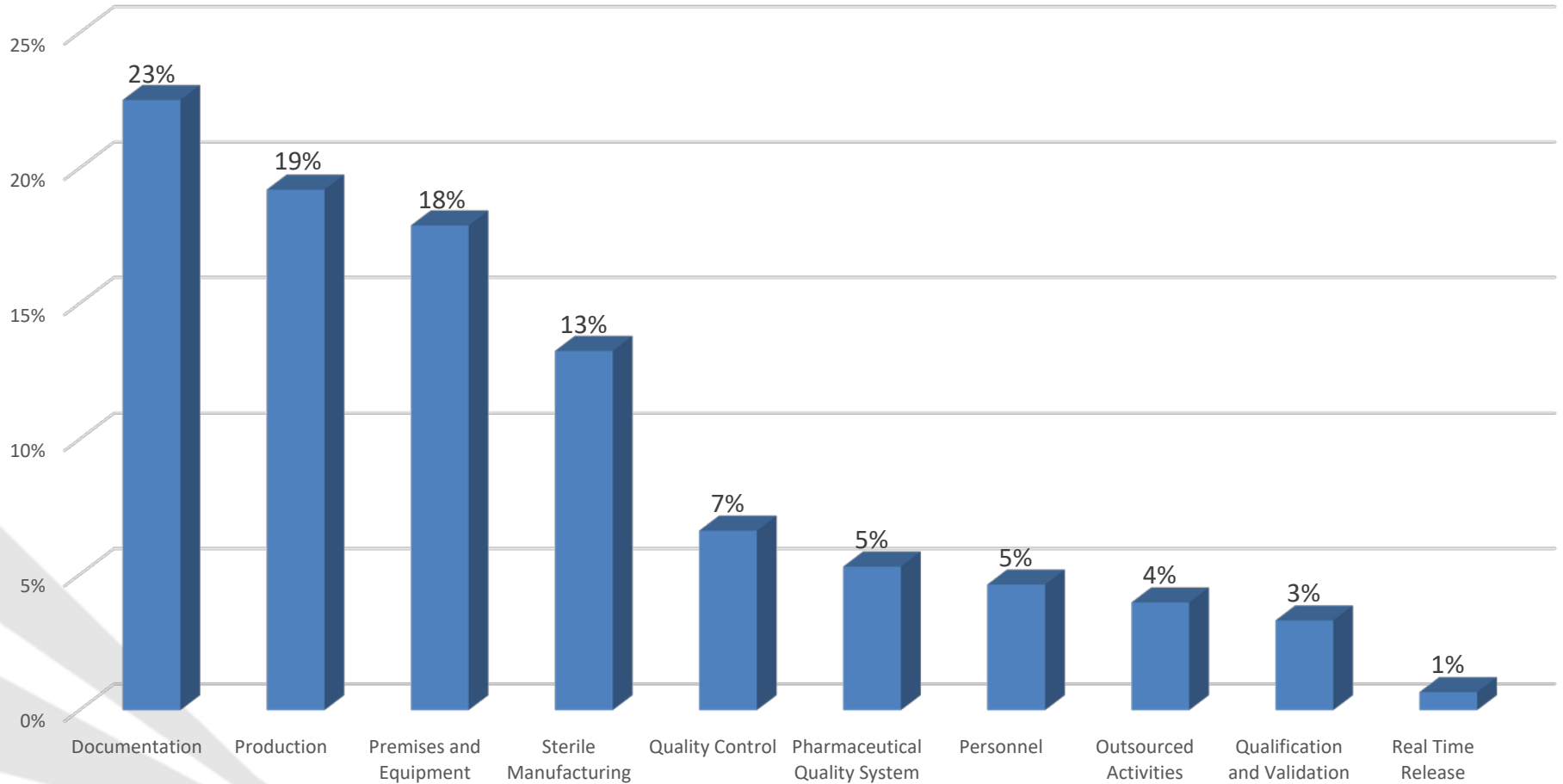
# GMP Inspection Trends

## Top 10 GMP Non-Conformities Raised for All Manufacturers in Year 2019



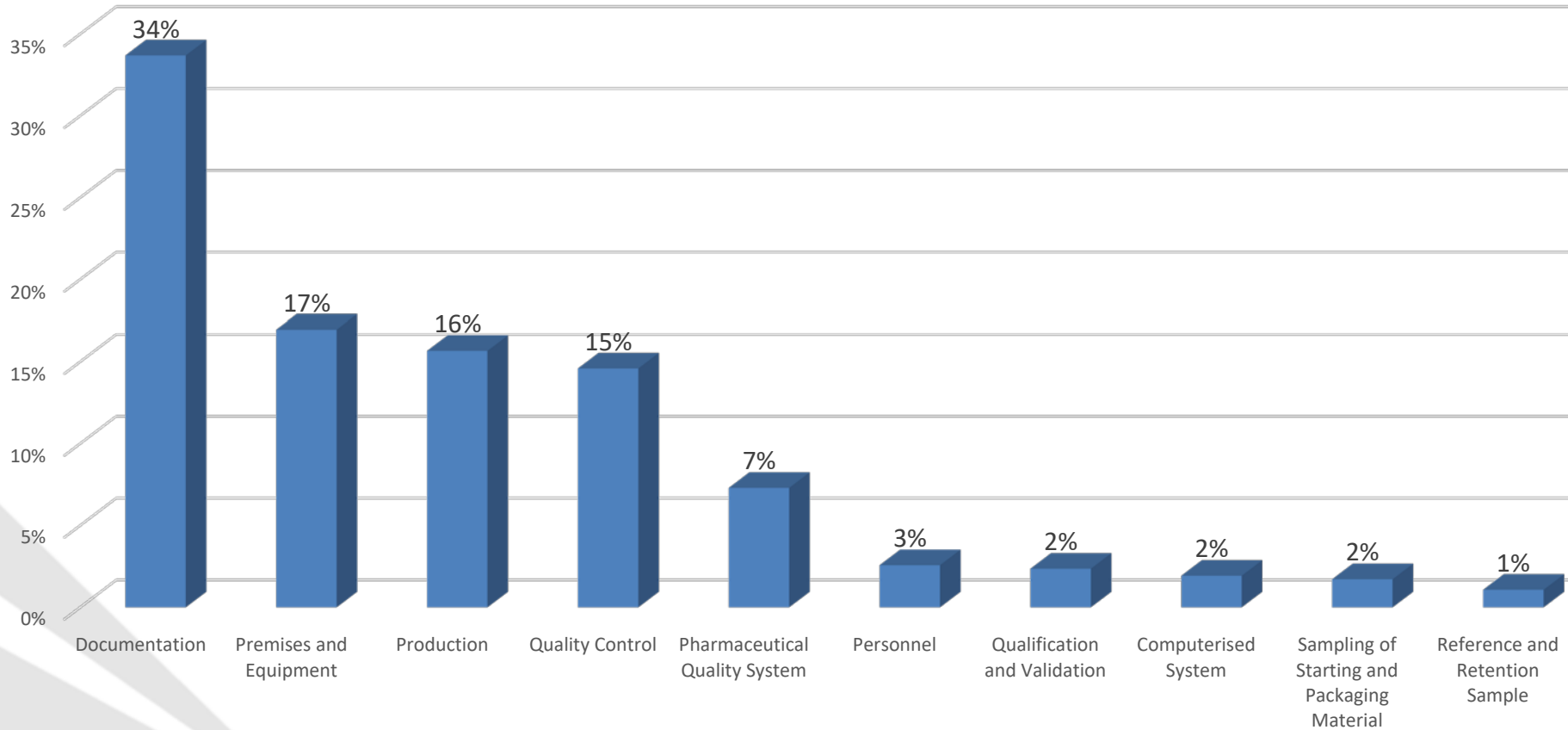
# GMP Inspection Trends

## Top 10 GMP Non-Conformities Raised for Therapeutic Products and API Manufacturers in Year 2019



# GMP Inspection Trends

## Top 10 GMP Non-Conformities Raised for Complementary Health Product Manufacturers in Year 2019





# GMP Inspection Trends

## Top 10 GMP Non-Conformities Raised for Assemblers in Year 2019

