

# All about Pre-filled Syringe Systems

From Initial Development to Final Fill Finish

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# Agenda – DAY 1

## **Overview and Introduction into Pre-filled Syringe Market**

*Overview & Trends • Stakeholders • User's perspective*

## **Technical Aspects**

*Syringe • Plunger • Needle • Needle shield or Tip cap • Autoinjector •  
Regulatory guidelines and technical standards*

## **Overview & Introduction into Drug-Syringe Interactions**

*Aggregation • Degeneration • Oxidation • Viscosity • Bubbles*

## **Overview & Introduction to manufacturing Process of PFS**

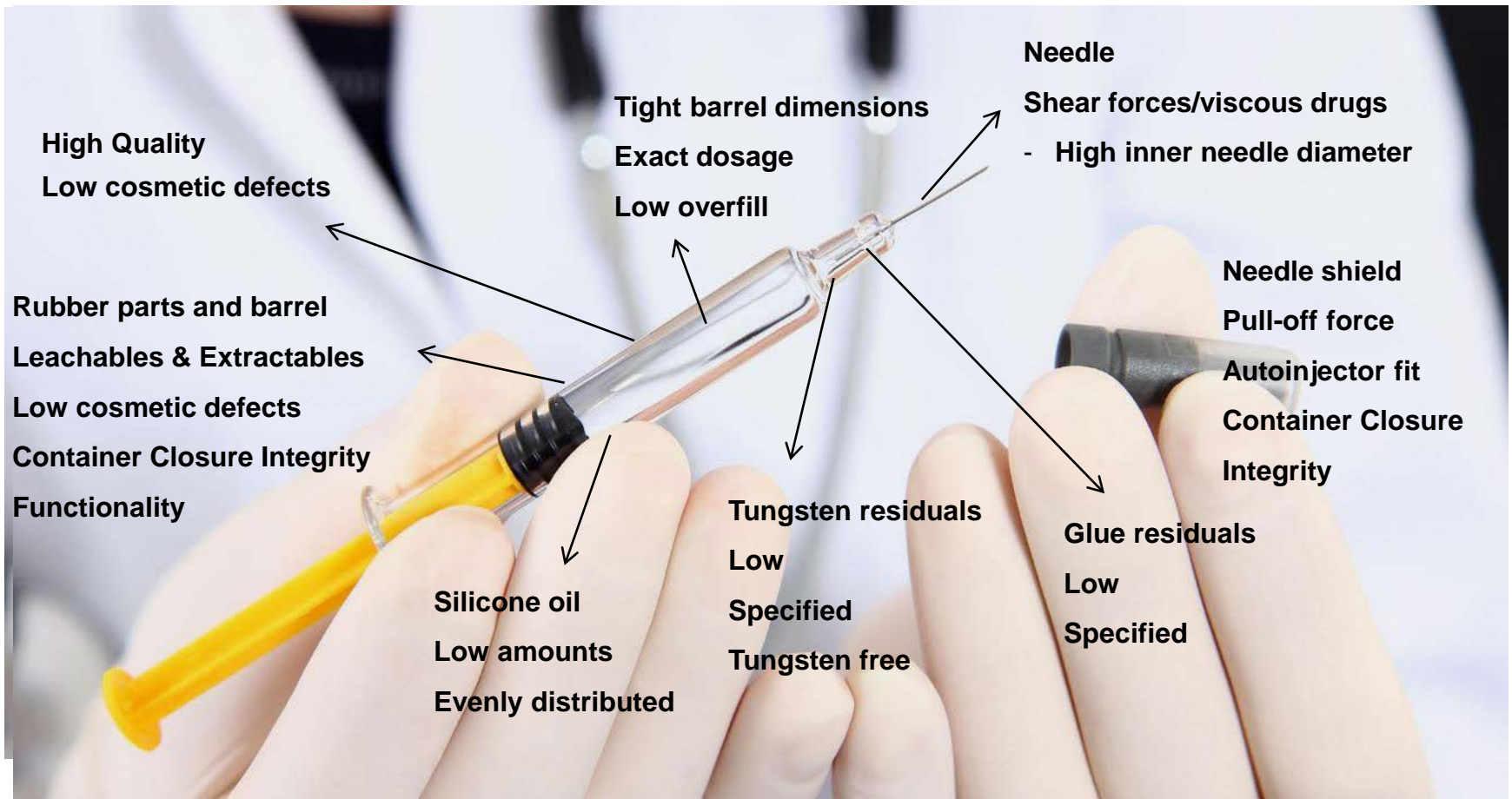
*Syringes Barrel Forming • Washing • Siliconization • Sterilization • Regulatory  
guidelines and technical standards ...*

## **Fill and Finish**

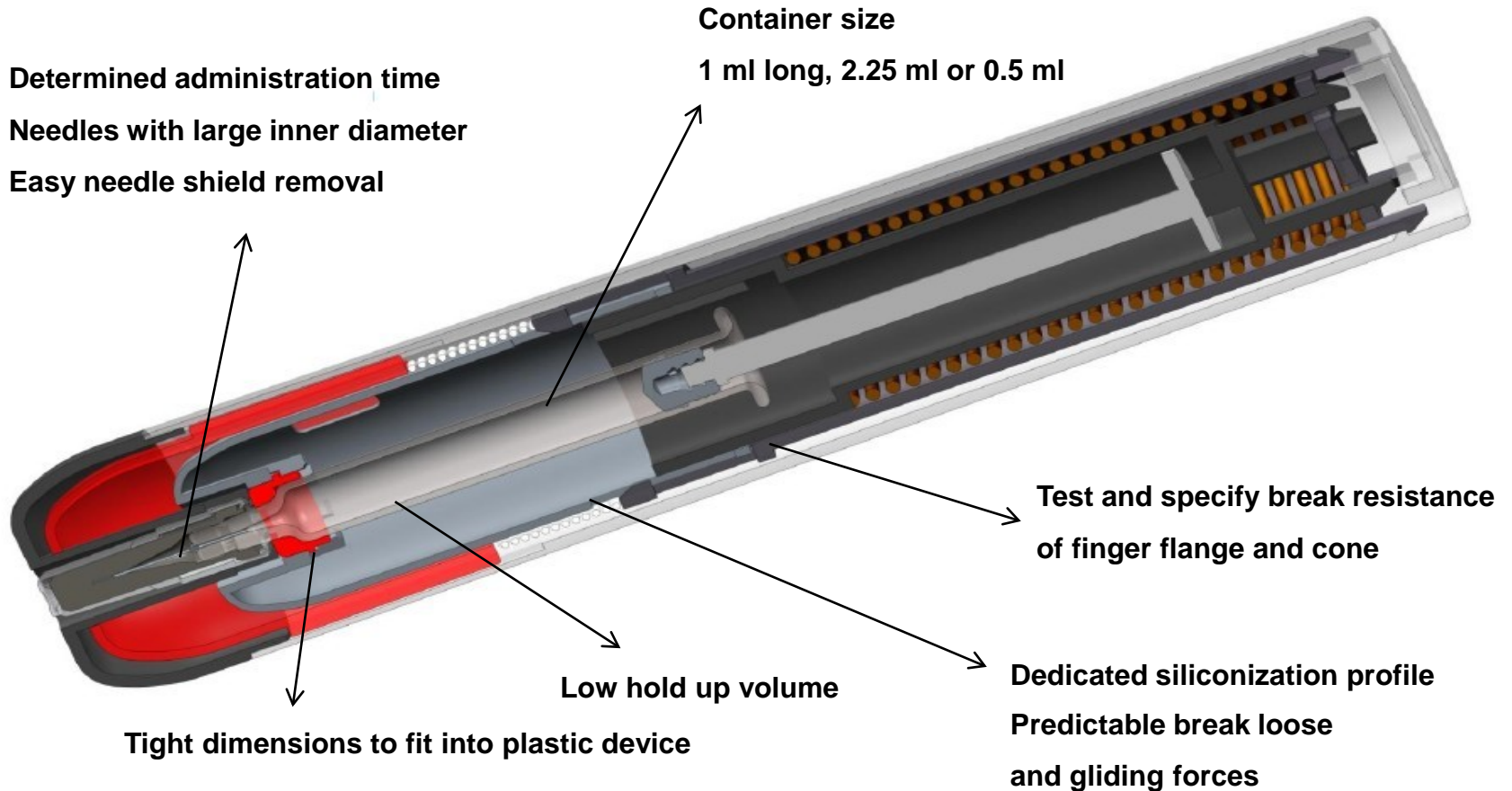
*Filling • Stoppering • Assembly • Technical Standards*

## **Hands-on Session 1**

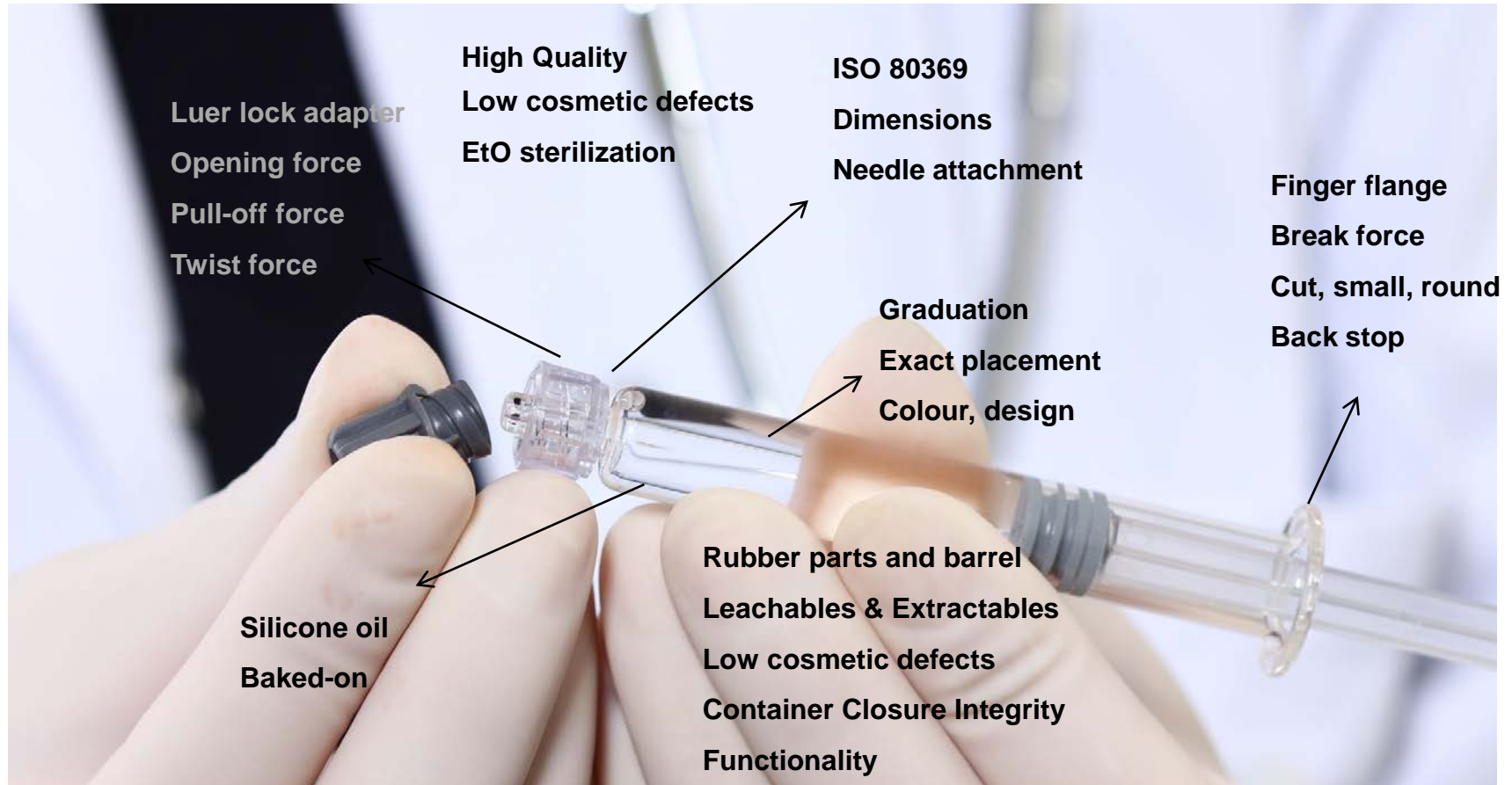
# Syringe as a system: Needle syringe



# Syringe system with Autoinjector



# Syringe as a system – Luer syringe



# Regulatory Guidelines

## Relevant norms and regulations

- **ISO 11040-4: Glass syringes ready for filling**
- **ISO 11040-5: Plunger stoppers**
- ISO 11040-6: Plastic syringes ready for filling
- ISO 11040-7: Nest & tub
- **ISO 11040-8: test methods for finished prefilled syringes**
- ISO 13926-1: Pen cartridges
- ISO 9187-1: Ampoules
- ISO 8362-1: Vials from tubular glass
- ISO 80369-7
  
- ISO 9001: Quality management
- ISO 15378: GMP Primary packaging
- 21 CFR 211 Subpart E – Control of Components and Drug Product Containers and Closures
- Ph.Eur. USP and JP
- DMF type III

0.5 ml	47.6	6.85	4.65	1/2
1.0 ml long	54.0	8.15	6.35	1/2
1.0 ml standard	35.7	10.85	8.65	1/2   5/8
1.5 ml	43.2	10.85	8.65	1/2   5/8
2.25 ml	54.4	10.85	8.65	1/2

- Dimensions
- Test methods





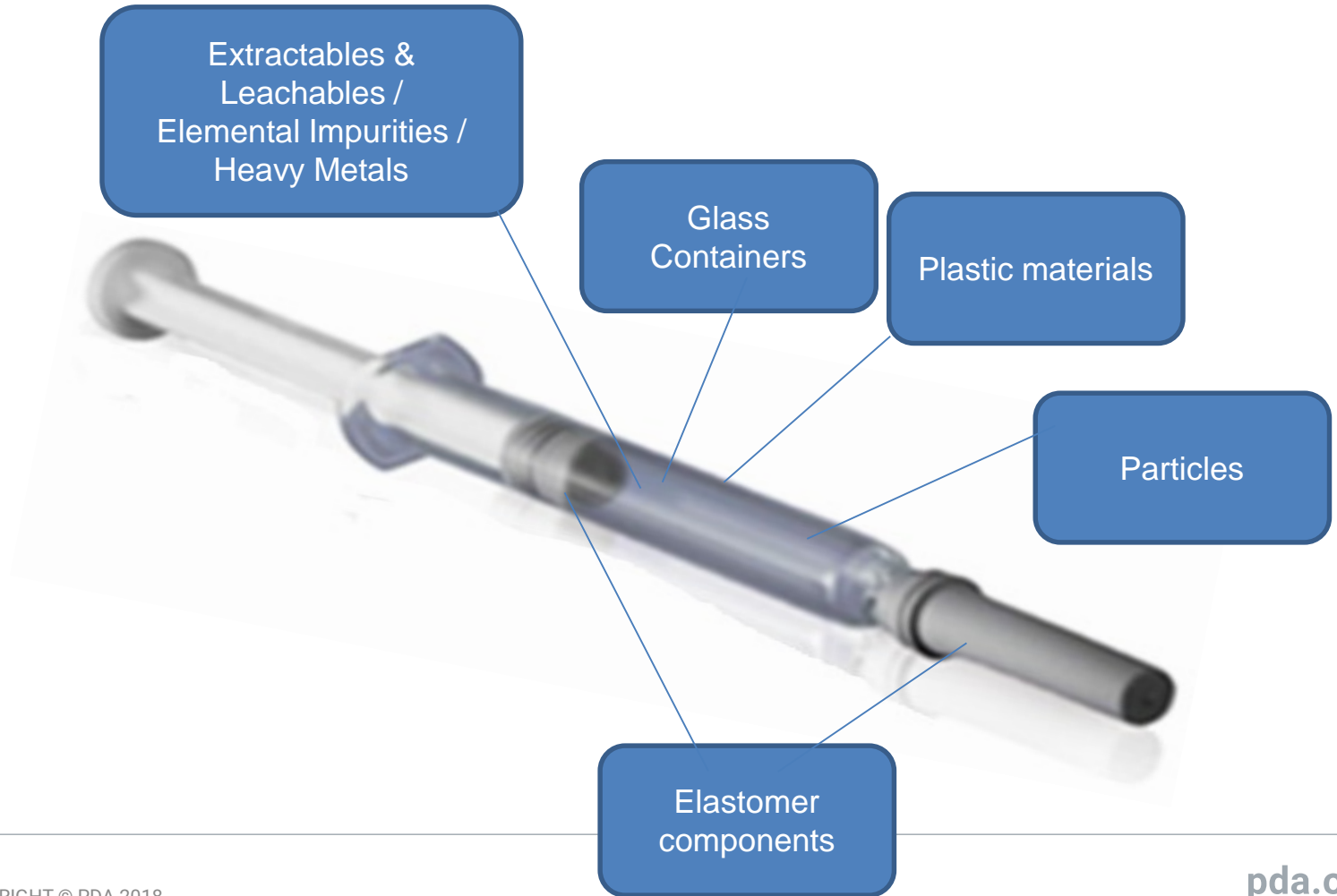
# Packaging Components Development



## Topics are getting more complex:

- Regulatory Environment
- Combination Products
- Safety Device
- Particles
- Elemental Impurities
- CCI
- Electronic Devices
- Extractables & Leachable
- Global pharmacopoeia harmonization

# Examples of Component Relevant Topics





# Global Pharmacopoeia

**USP**

United States  
Pharmacopeia

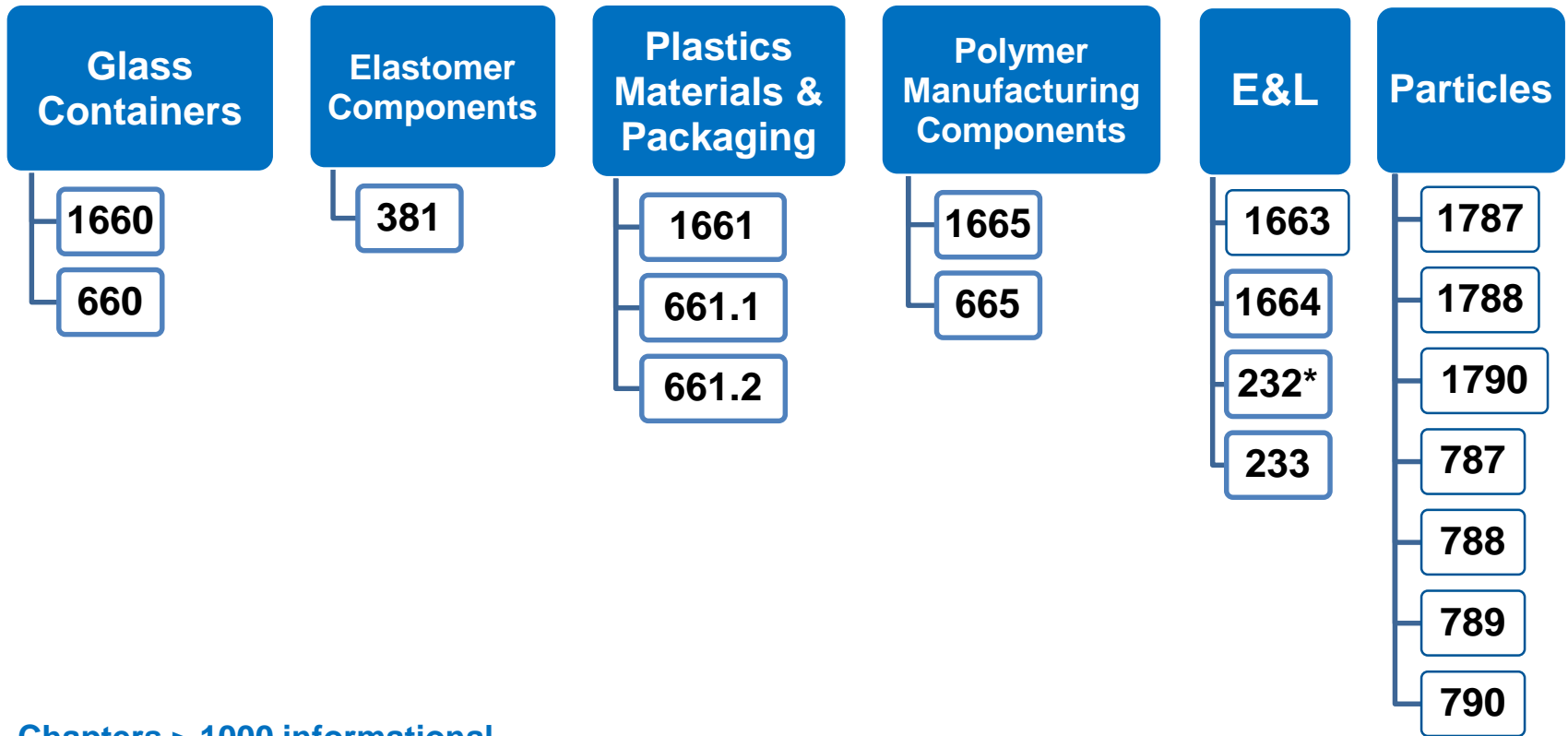
European  
Pharmacopeia

**PHARMACOPEIA**  
OF THE PEOPLE'S REEPUBLIC OF CHINA

**JP**

Japanese  
Pharmacopeia

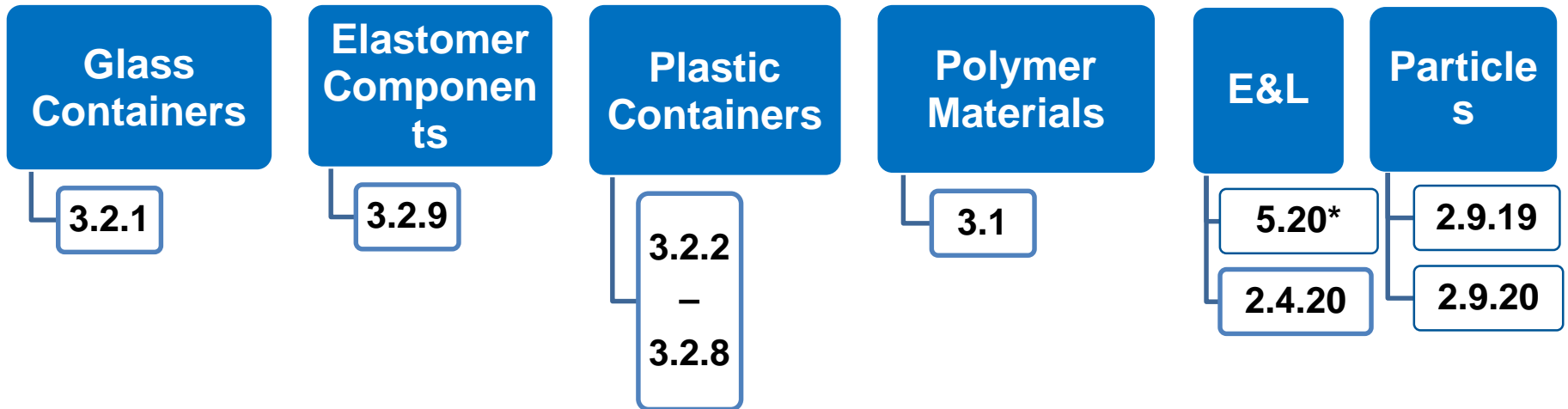
# Overview of Relevant USP Chapters



**Chapters > 1000 informational**  
**Chapters < 1000 mandatory if required by monograph**  
 \* <231> has been deleted

# Overview of Relevant Ph Eur Chapters

European  
Pharmacopeia

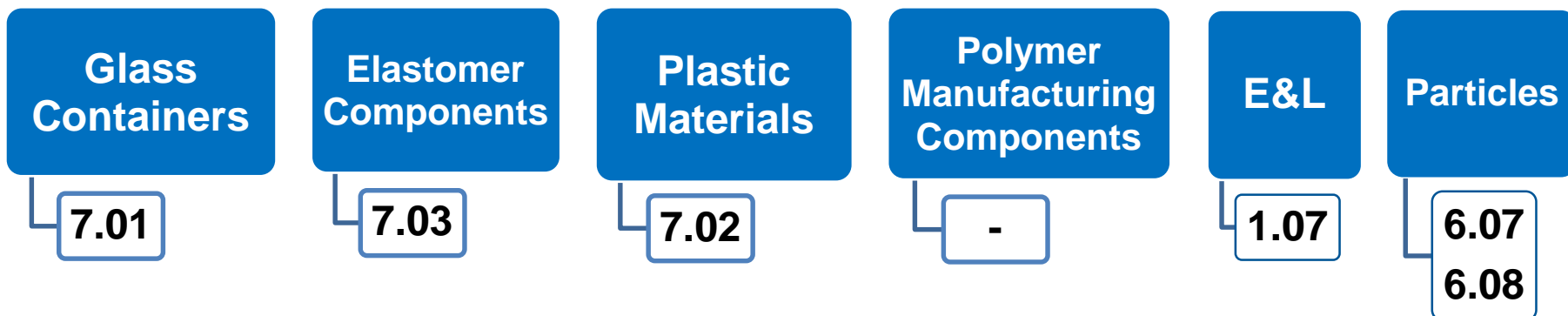


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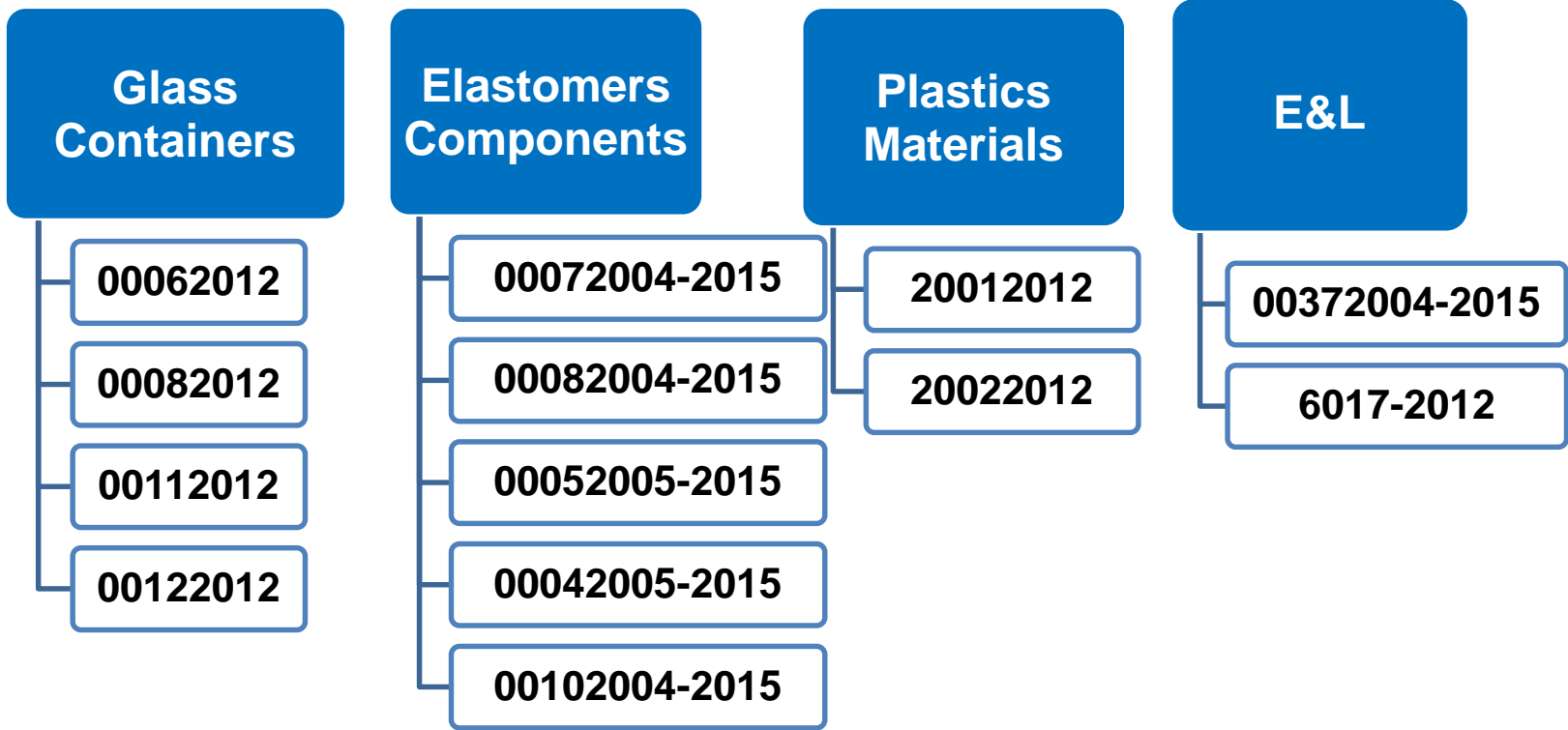
# Overview of Relevant JP Chapters

**JP**

Japanese  
Pharmacopeia



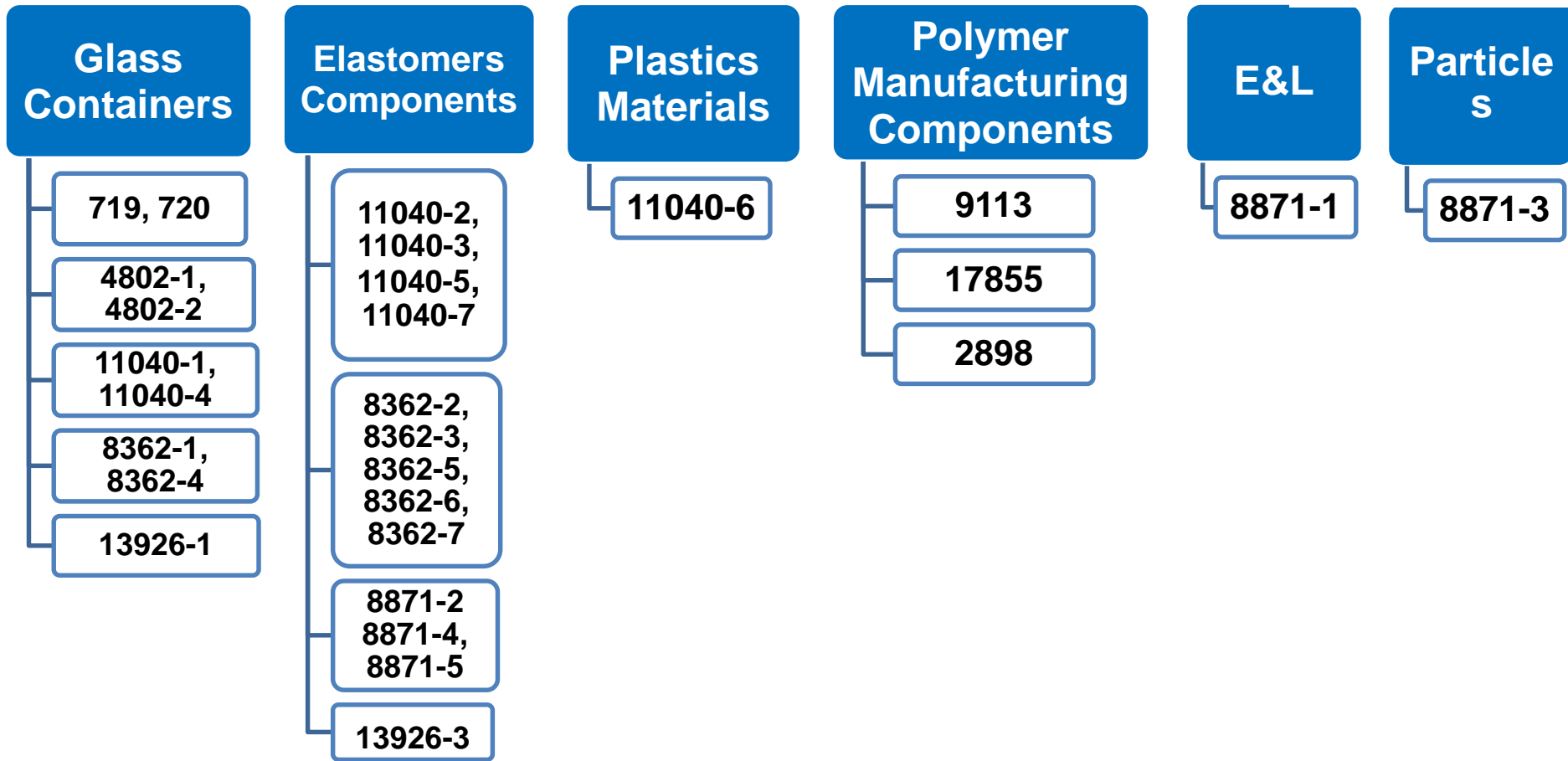
# Overview of Relevant YBB Standards



**YBB standards currently more relevant than ChP for packaging material**

# Extract of Relevant ISO Standards

# ISO



# Global Comparison of Glass Chapters



Purpose	Paragraph	USP <660>	Ph Eur 3.2.1	JP 7.01	YBB
Introduction	Definition of Glass Types	✓	✓	—	✓
Identification	Glass Grains Test	✓	✓	✓	✓
Chemical Feature	Surface Glass Test	✓	✓	—	✓
Physical Feature	Light Transmission	✓	✓	✓	✓
Potential Extractable	Arsenic extraction	✓	✓	Only iron for light-protective containers	✓



# Ongoing Revisions in Glass Chapters



**USP**

**European  
Pharmacopeia**

**JP**  
Japanese  
Pharmacopeia

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OF CHINA**

- Including Aluminosilicate glass?
- Stating autoclaving procedure more precisely
- Updating light transmission test
- Redirecting and updating arsenic test
- Addressing elemental impurities

- Stating autoclaving procedure more precisely
- Addressing elemental impurities

Hasn't been updated in over 35 years

Ongoing revisions in all topics  
With a strong attention to the global revision process and discussion