

PDA D/A/CH Webinar:

Primary Packaging Essentials: From Drug to Container.



PDA D/A/CH Chapter

PDA D/A/CH - Open Access, Discourse & Information for the pharmaceutical industry in the D/A/CH Region

- Founded and constituted in 2024.
- PDA D/A/CH is a PDA chapter with a strong focus on networking and engagement in the D/A/CH Region.
- Webinar Series First of many events in the D/A/CH Region

Mission statement:

„Our mission is to enable open and comprehensive knowledge exchange among individuals at different career stages and with diverse levels of experience in the pharmaceutical industry. Thereby, we promote intergenerational and interdisciplinary dialogue. We achieve this through networking, mentoring, and local events.“

PDA D/A/CH is a newly founded Chapter. Volunteers are always welcome.



4 Committees:

- Communications & Social Media
- Programs & Events
- Membership
- Early Career Professionals



For people who are interested in volunteering and future endeavours follow us on LinkedIn or contact us via dach@pdachapters.org

PDA Membership is highly attractive opportunity for young and experienced professionals in the pharmaceutical industry

	Essential	Plus	Premium
Standard Member	\$150	\$250	\$350
Academic, Early Career, and Emerging Economy	\$75	\$125	\$245
Health Authority, Retired	Free	Free	\$175
Students	Free	Free	Free
Membership Directory	X	X	X
Vote in PDA elections and on proposed bylaws changes	X	X	X
PDA Letter Online	X	X	X
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PDA Technical Publications Portal - view and annotate the full collection of TRs and PtCs online.		X	X
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Download new TRs/Surveys/PtC for free within 30 days			X
PDA Technical Reports - 1 free download of your choice from the existing TR/Survey/PtC library per year.			X
PDA Journal - Unlimited Access			X



The People behind this Webinar series



Julian Petersen –
President PDA
D/A/CH, Groninger



Thorsten Haefner –
Chair Event
Committee, PSM



Marc Schneider –
Co-Chair Event
Committee, BioNTech



Dennis Augustin – Chair
Communication
Committee, AbbVie

Today's Presenters



- Florence Buscke
- Head of Global Product Management at SCHOTT Pharma



- Ana Kuschel
- Principal Scientific Affairs at West Pharmaceutical Services

Agenda

> Introduction

> Ampoules

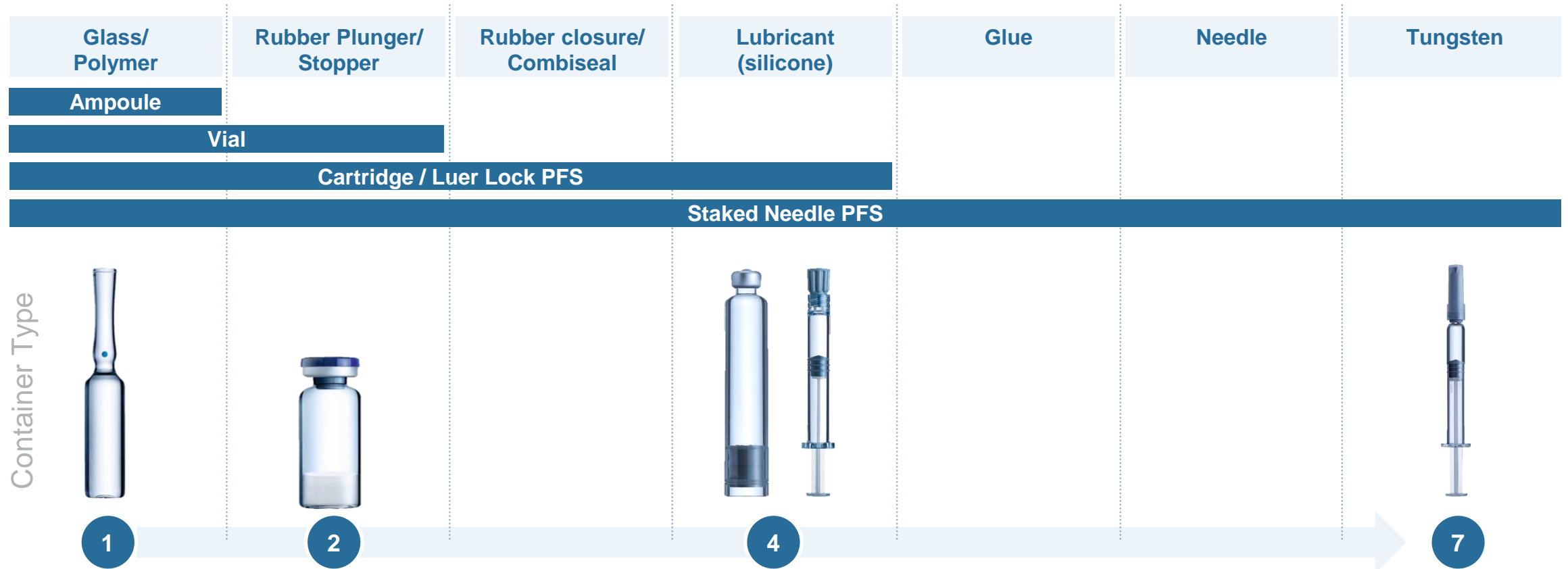
> Vials

> Syringes

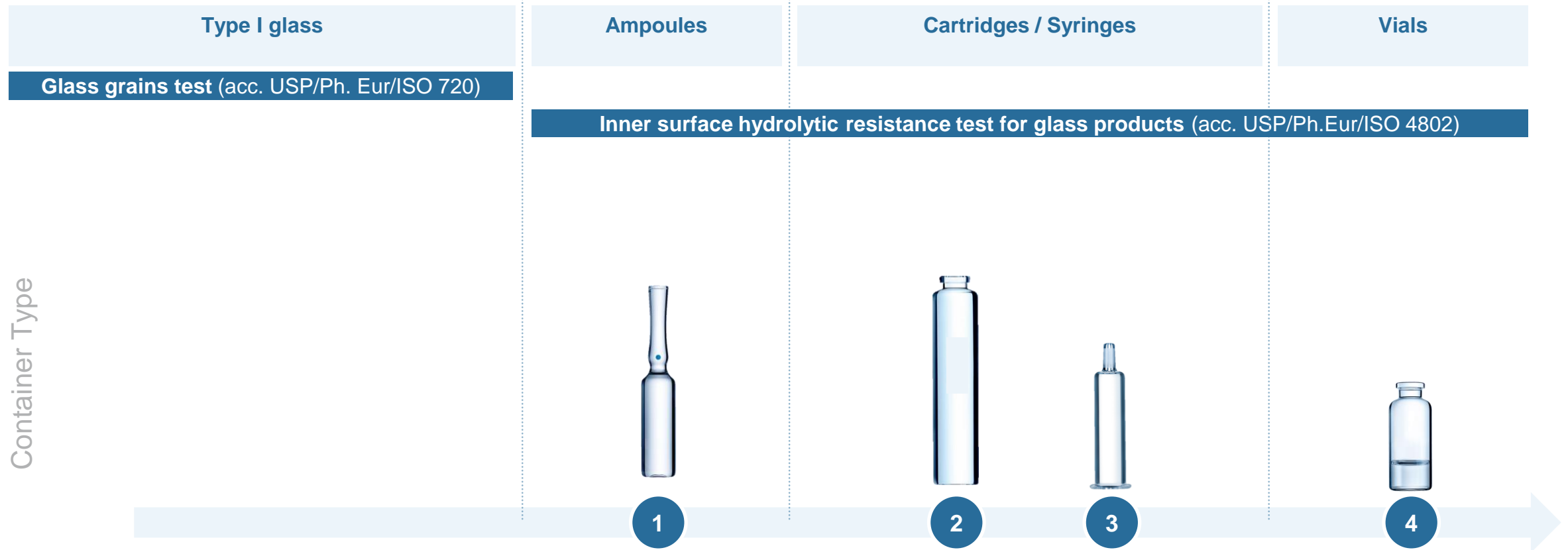
> Cartridges

> Take away

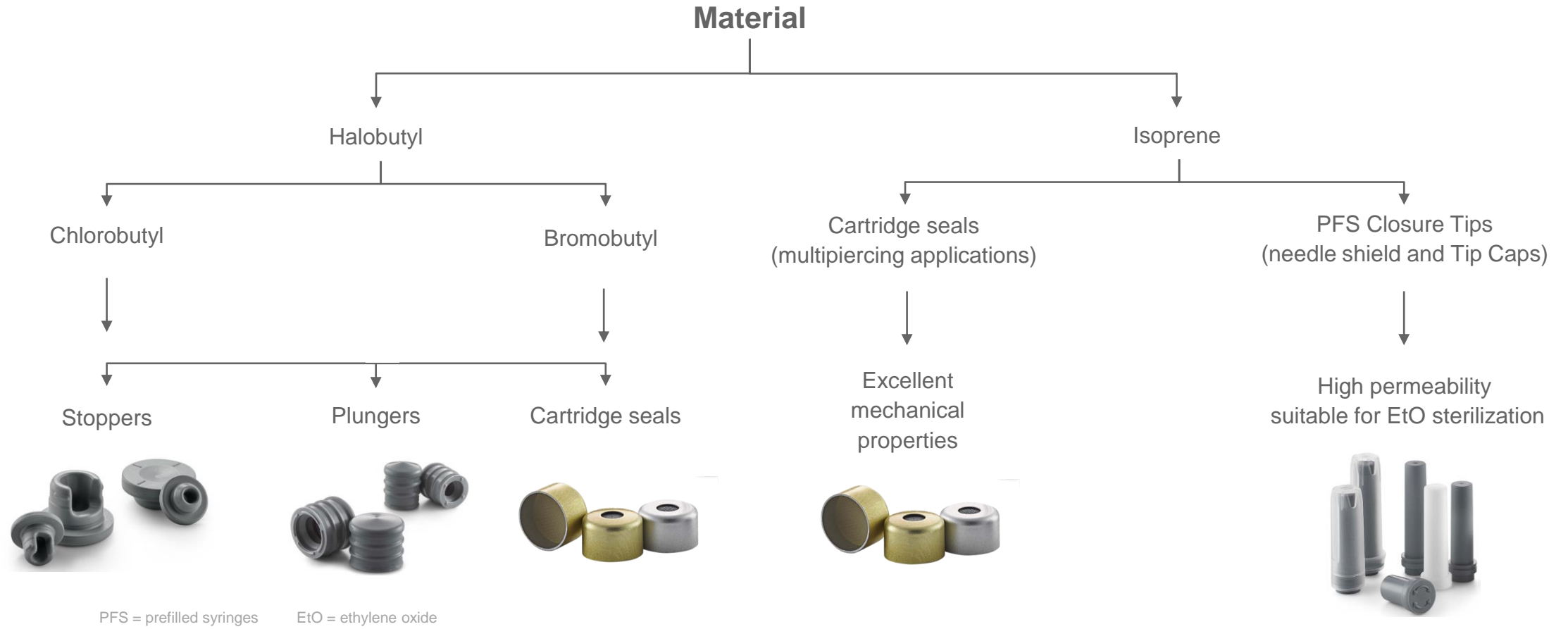
Decision | Stability of system



Decision | Stability glass or polymer



Decision | Rubber materials



Regulatory framework



Compendial in general:

- USP 381 / 1381
- USP 382 / 1382 *
- USP 660 / 1660
- JP 7.03
- EP 3.2.9

* will be official 2025



PQRI recommendations on E&L for parenteral drug products

- PQRI Safety Thresholds and Best Demonstrated Practices for E&L in Parenteral Drug Products (ISBN 978-1-945584-30-5)



Elemental Impurities in Drug Product:

- ICH Q3D
- Ph Eur 5.20
- USP <232> and <233>



Particles:

- USP 787 / 1787
- USP 788 / 1788
- EP 2.9.19 and 2.9.20



Biological evaluation of medical devices:

- ISO 10993-17 Establishment of allowable limits for leachable substances
- ISO 10993-18 chemical characterization



EU GMP Annex 1:

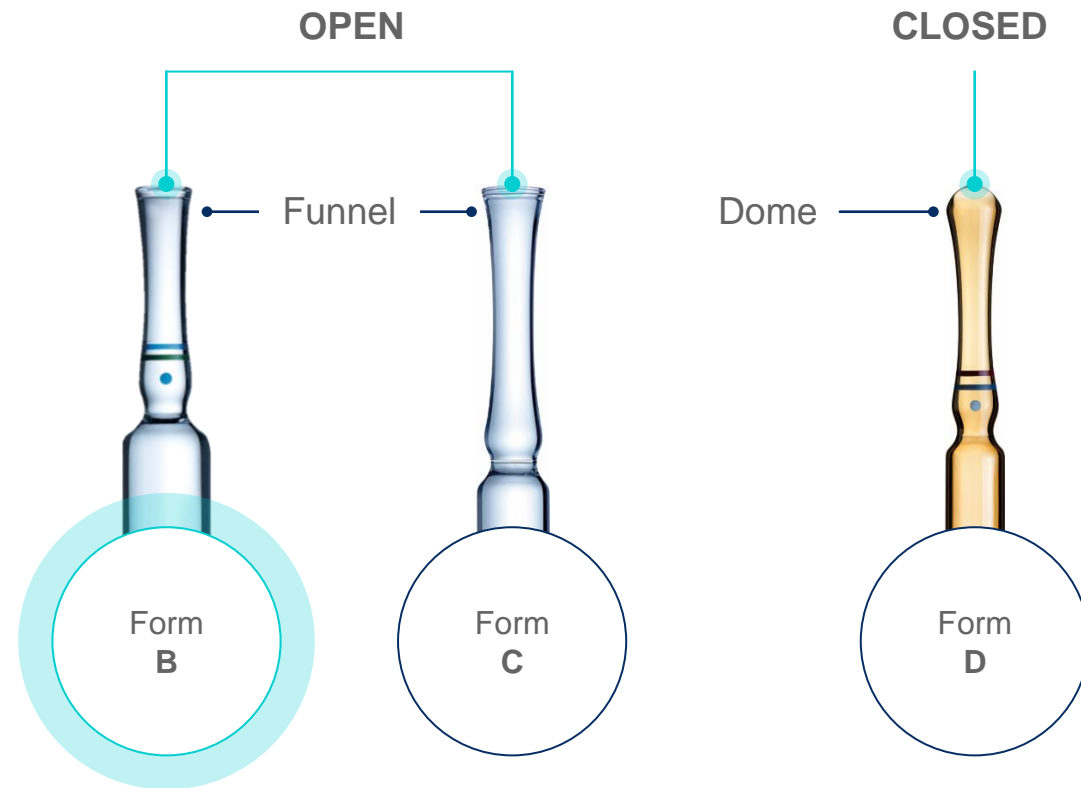
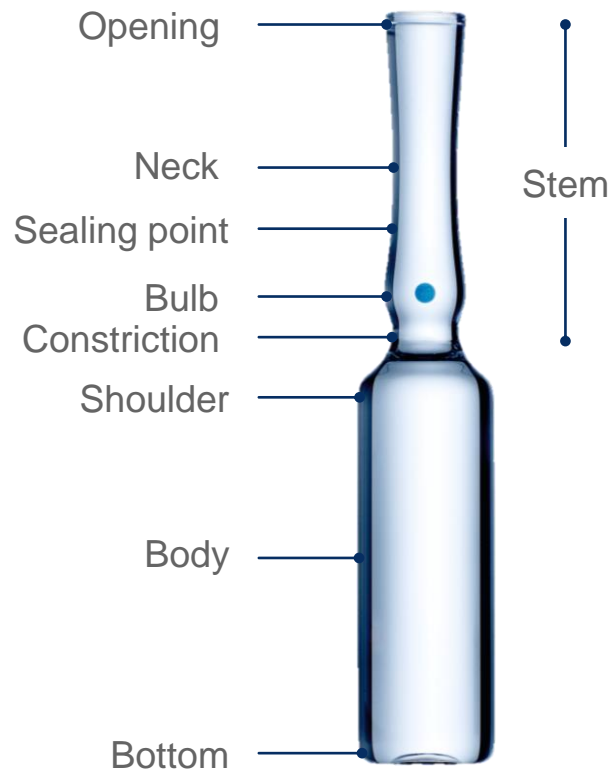
- Particles and microbiological contamination
- Sterility assurance
- Container closure integrity





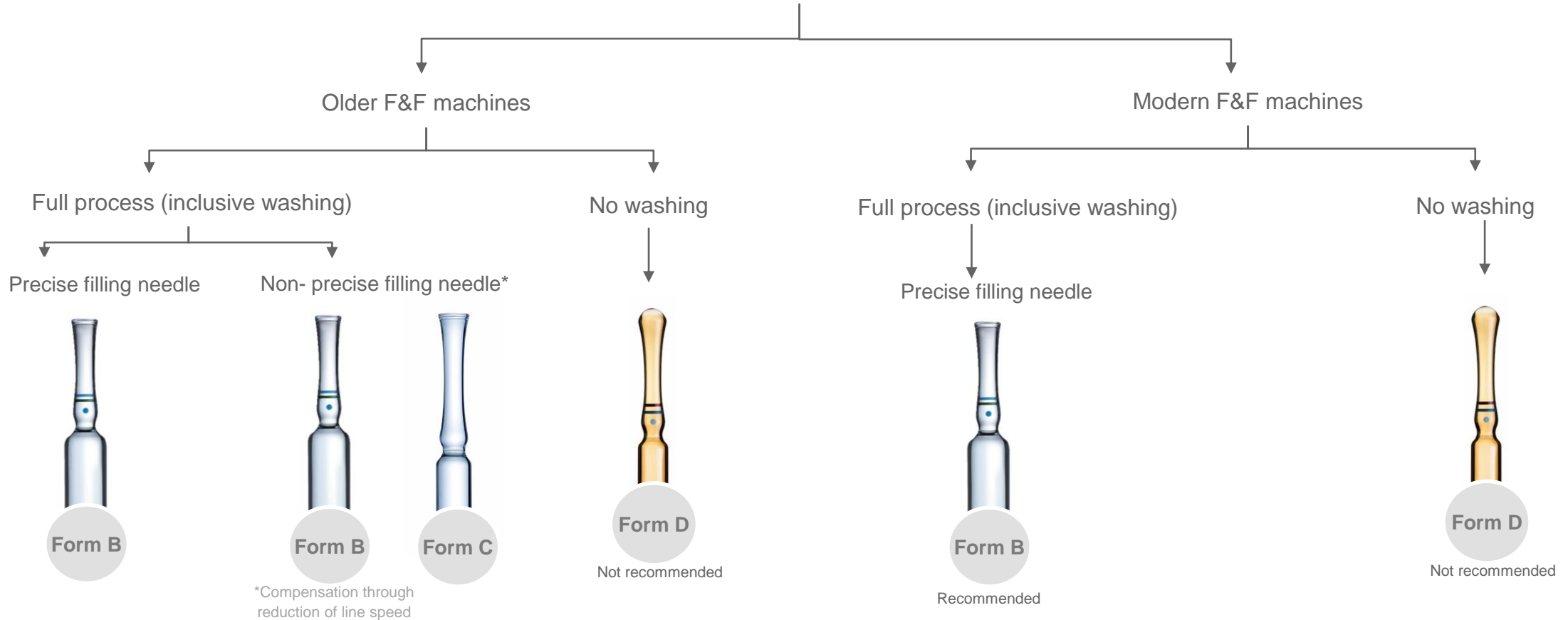
Ampoules

Ampoules - anatomy

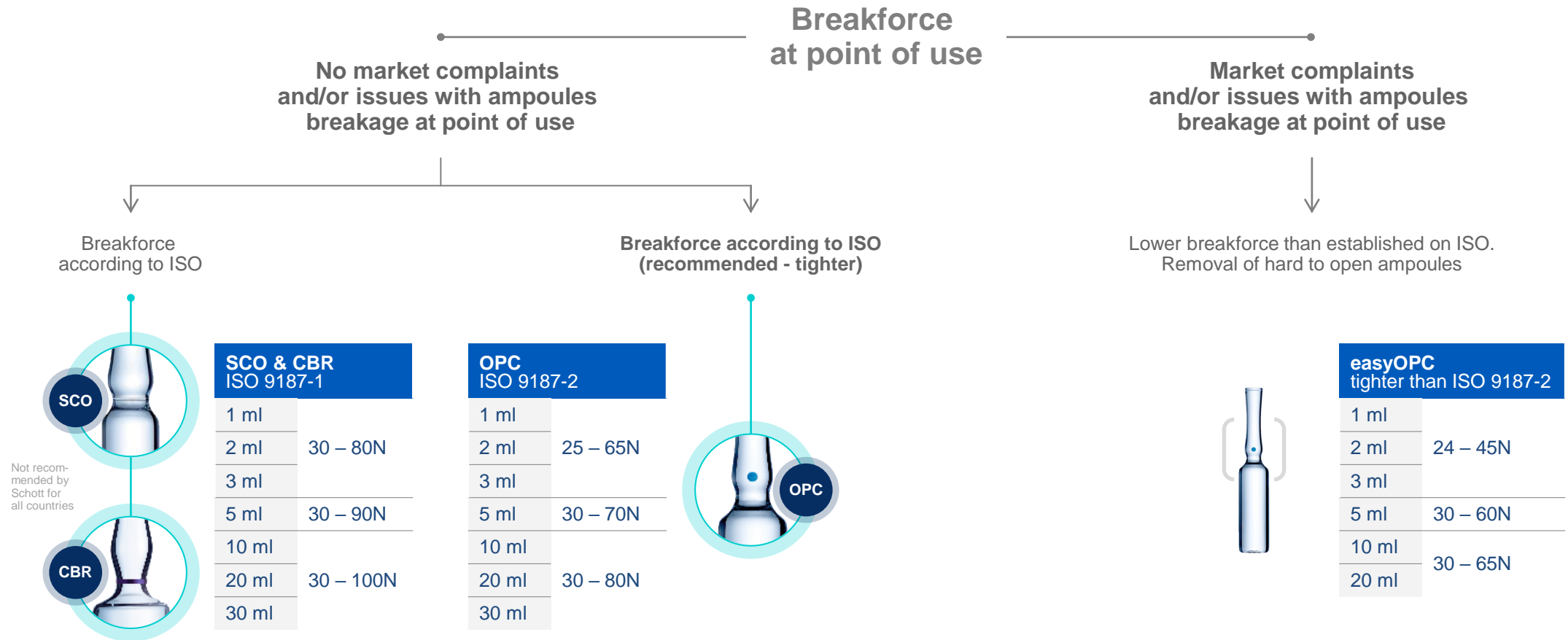


Decision | Form factor

Machinability



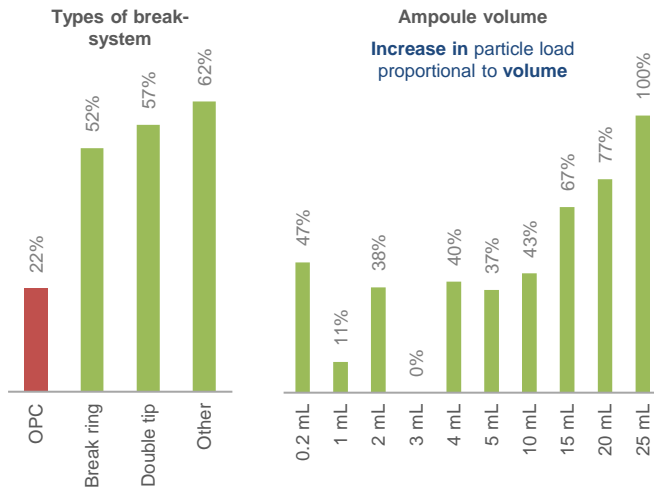
Decision | Ease of opening



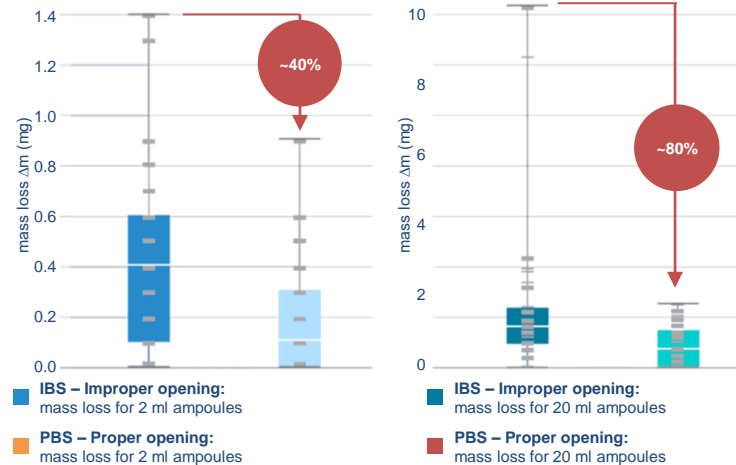
Relevant break-system

OPC break-system has **significant less glass particles formation during opening** than other break-systems

Increase in glass particles
according to break-systems and volumes*



15% of OPC ampoules shatter
due to incorrect opening* and majority
show more glass particles



Opening SCHOTT OPC Ampoules – YouTube**

Solution:

Use of best break system and combine with right opening technique

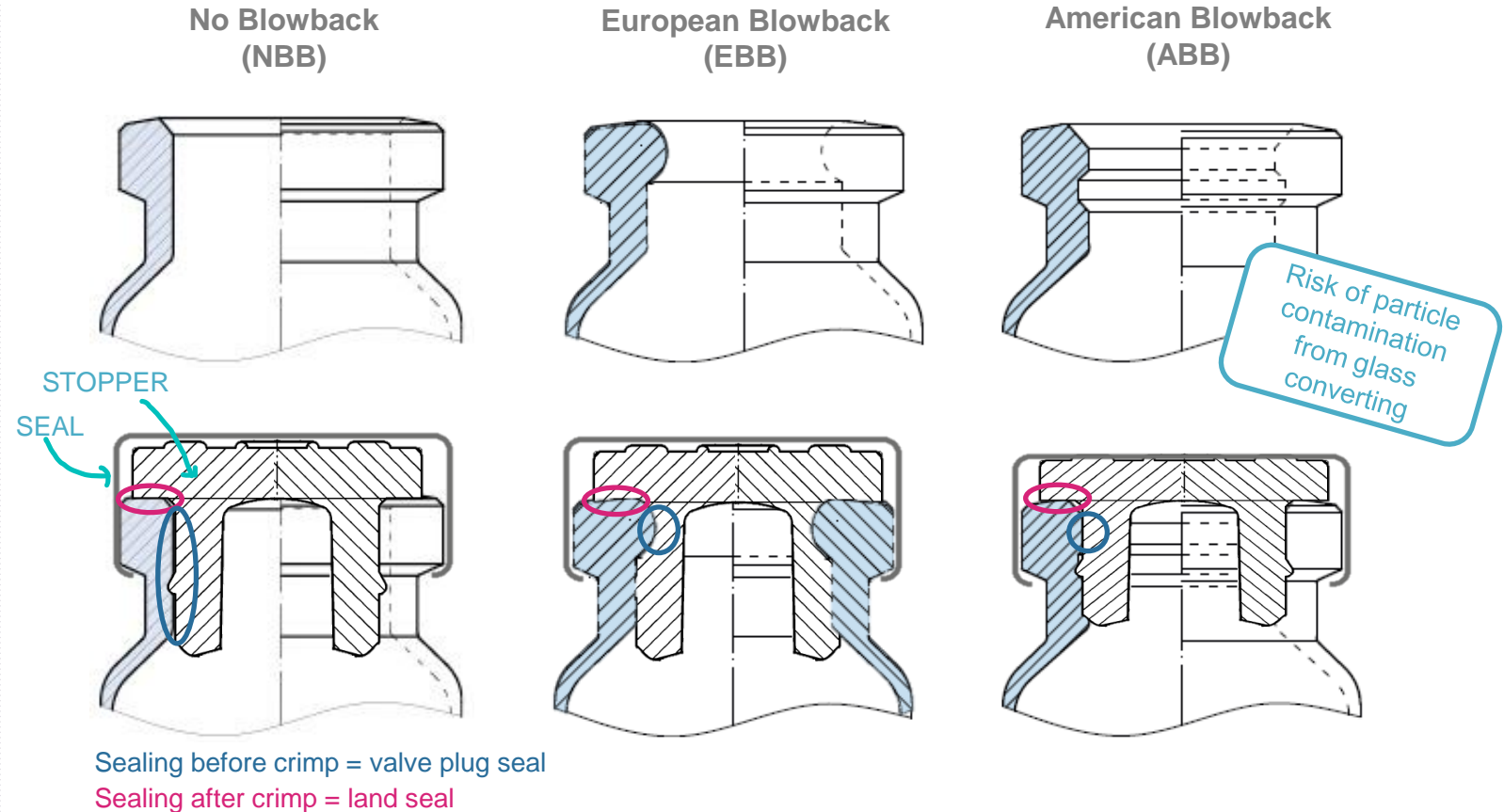
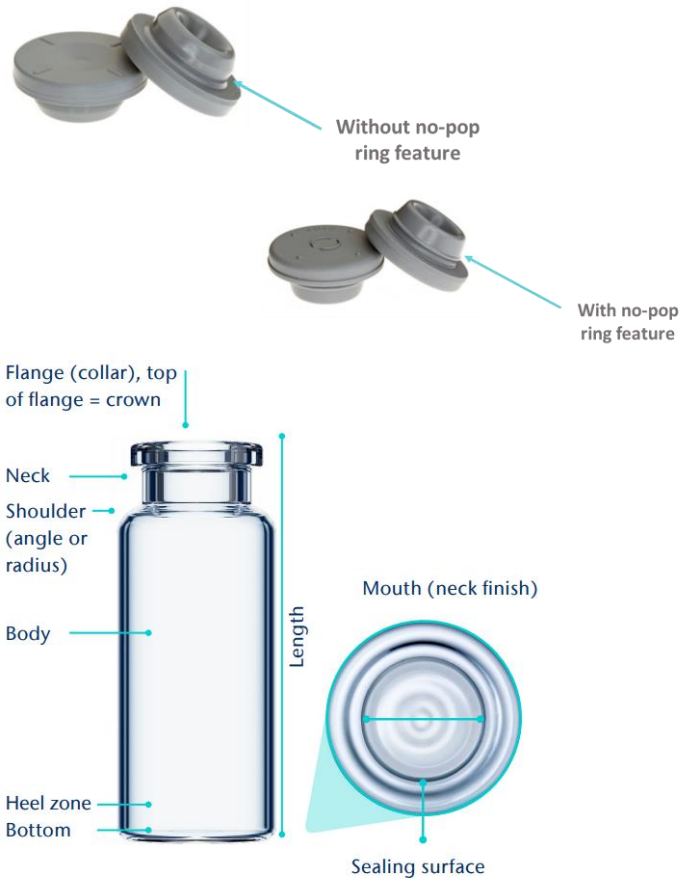
*Results from OMCL market surveillance study on the breaking of glass ampoules across 9 European countries (n=2190);

** Videos are also available in Mandarin, Portuguese & Spanish



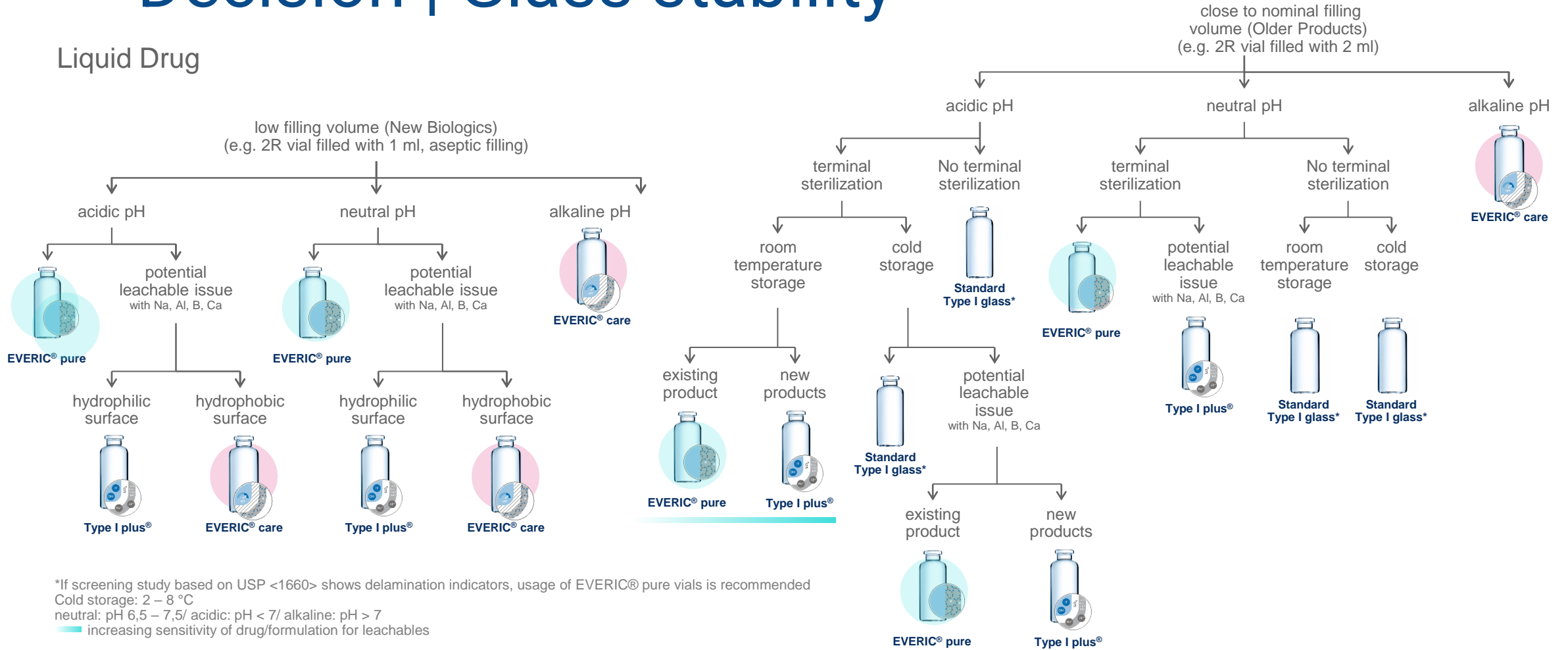
Vials

Decision | Container closure integrity



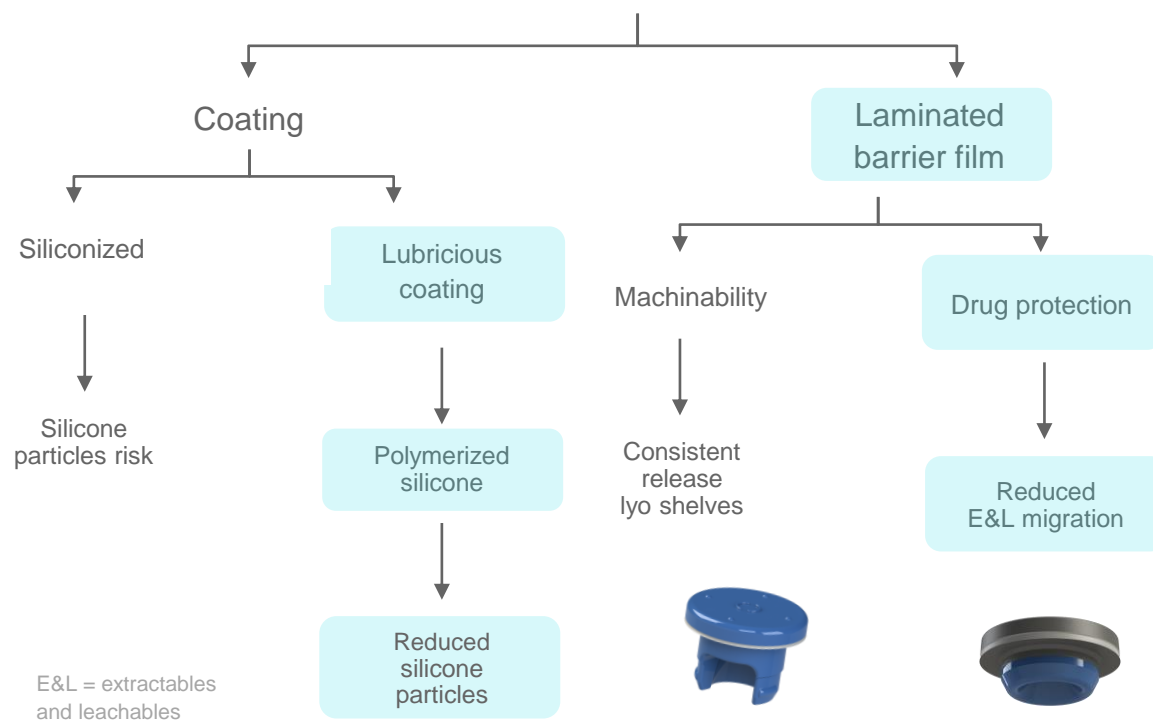
Decision | Glass stability

Liquid Drug

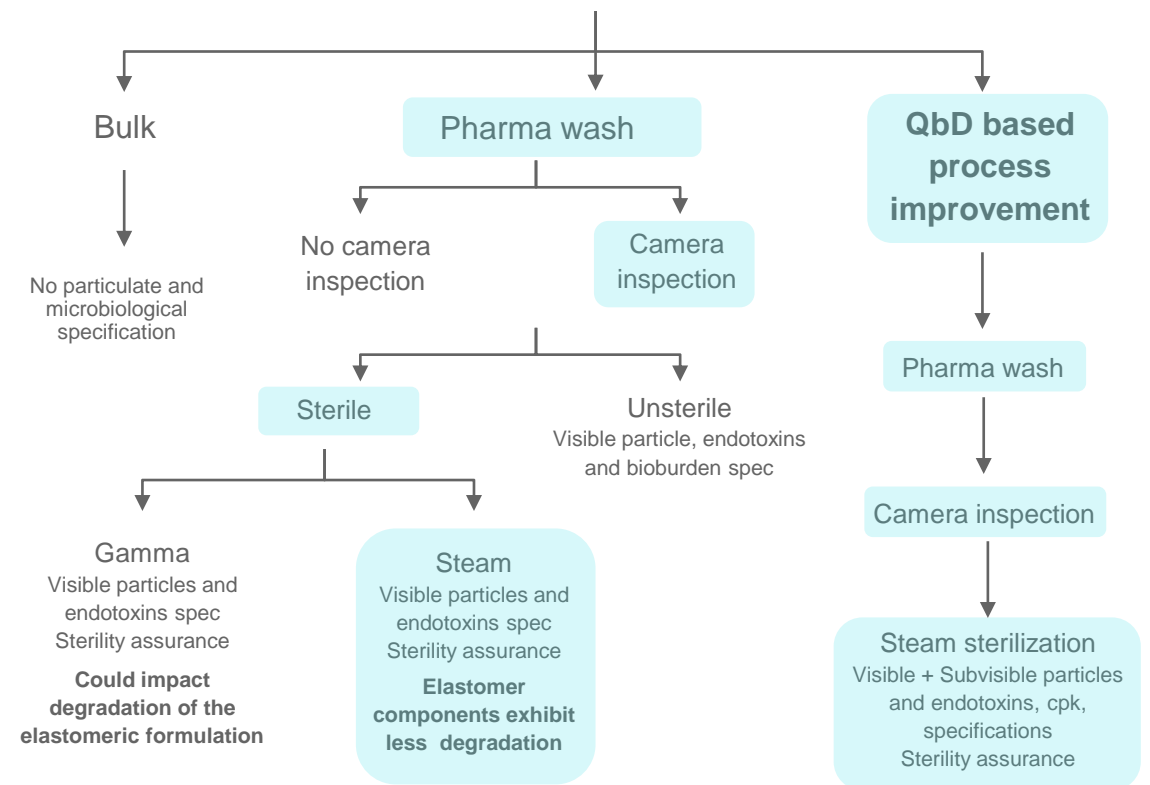


Decision | Vial rubber components

Properties



Process



Source: West TR 2000/026 B2-Coating Quantitative Particle Analysis, West TR 2019/210 FluroTec® Products Protecting Drug Product Quality and Safety, West TR 2011/140 Impact of Steam and Gamma Processing on Elastomers, West TR 2008/129 Global West's Envision™ Process Validation Summary, West TR 2004/107 LyoTec® Stopper Adhesion to Freeze Dryer Shelves

System functional performance tests

Residual Seal Force

Flip-Off Seal Cap Removal Force

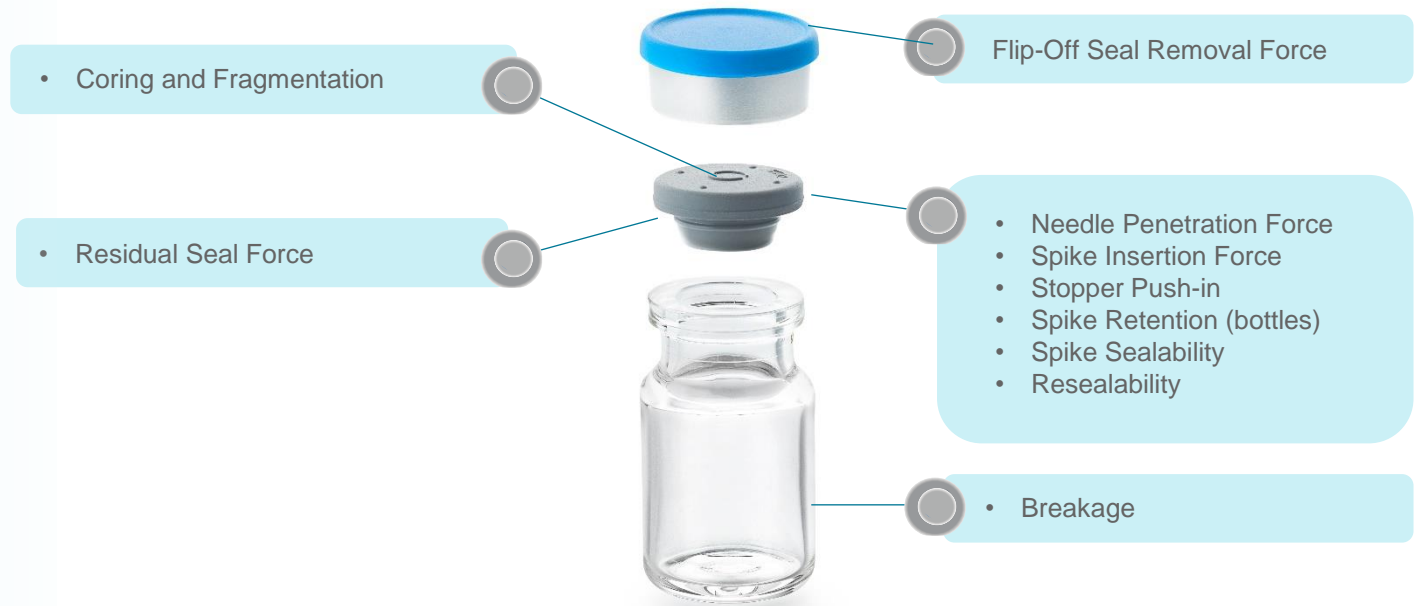
Penetration Force

Fragmentation

Needle Self-Sealing Capability (CCI)

Spike Retention and Sealability

Determination of Insertion Force of Stoppers



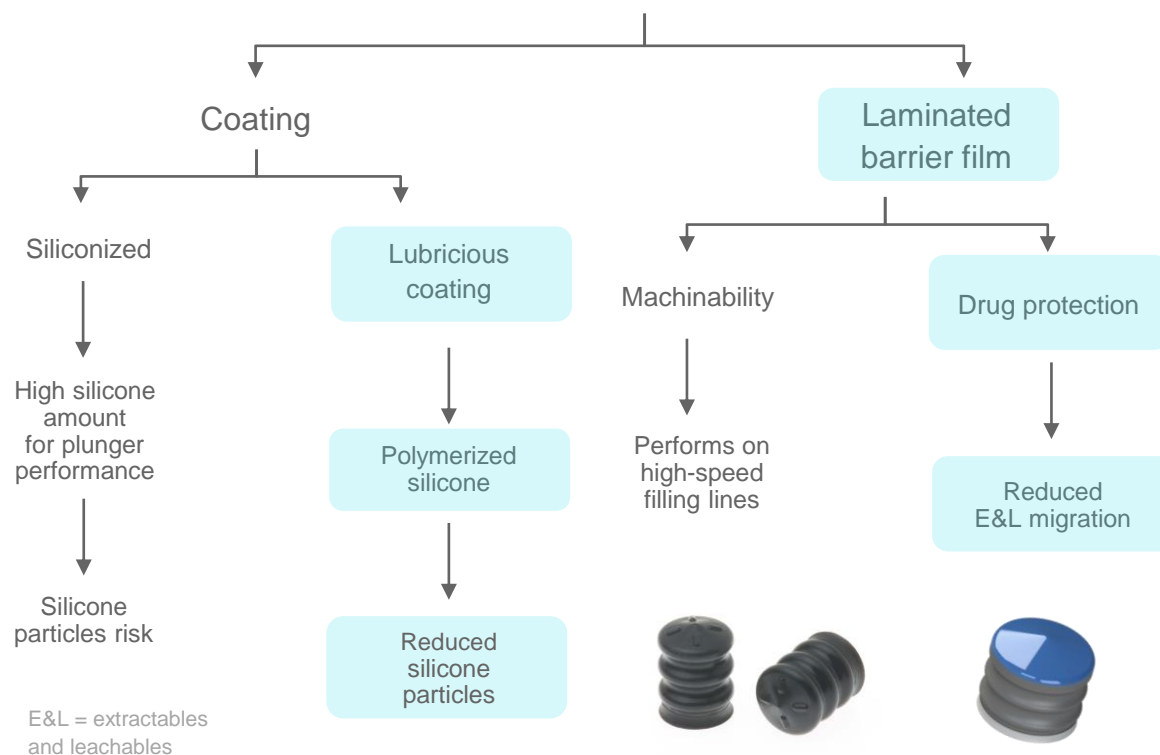
Consider all interfaces as potential failure points



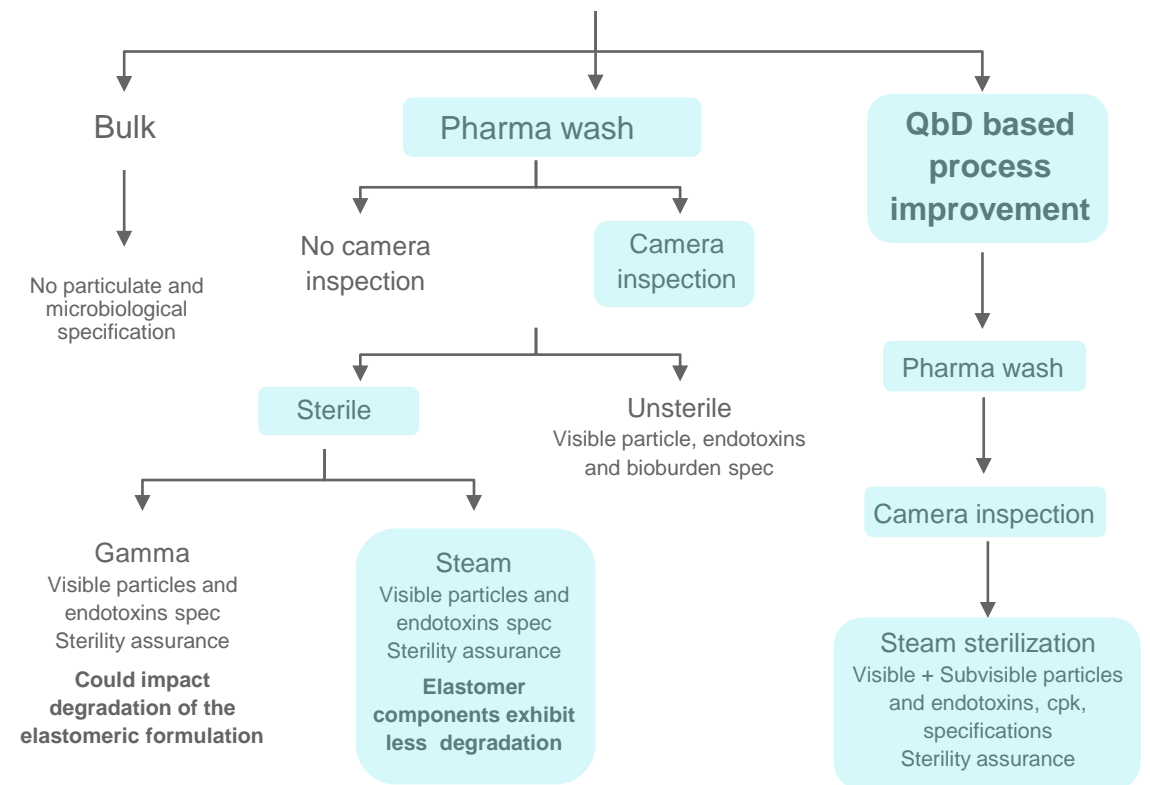
Syringes

Decision | Plunger rubber components

Properties

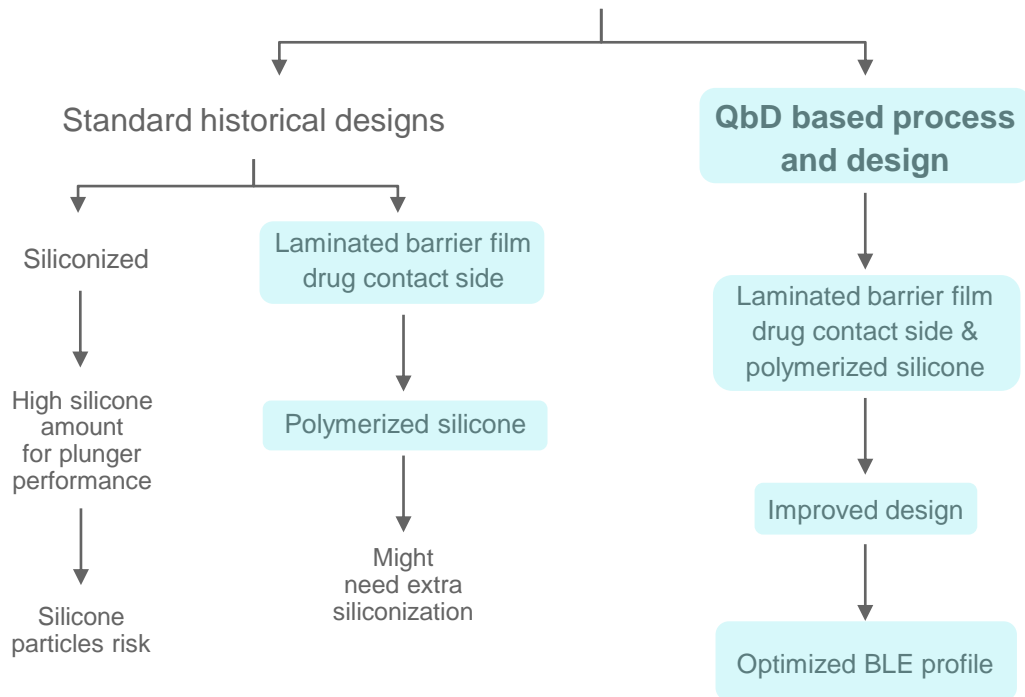


Process

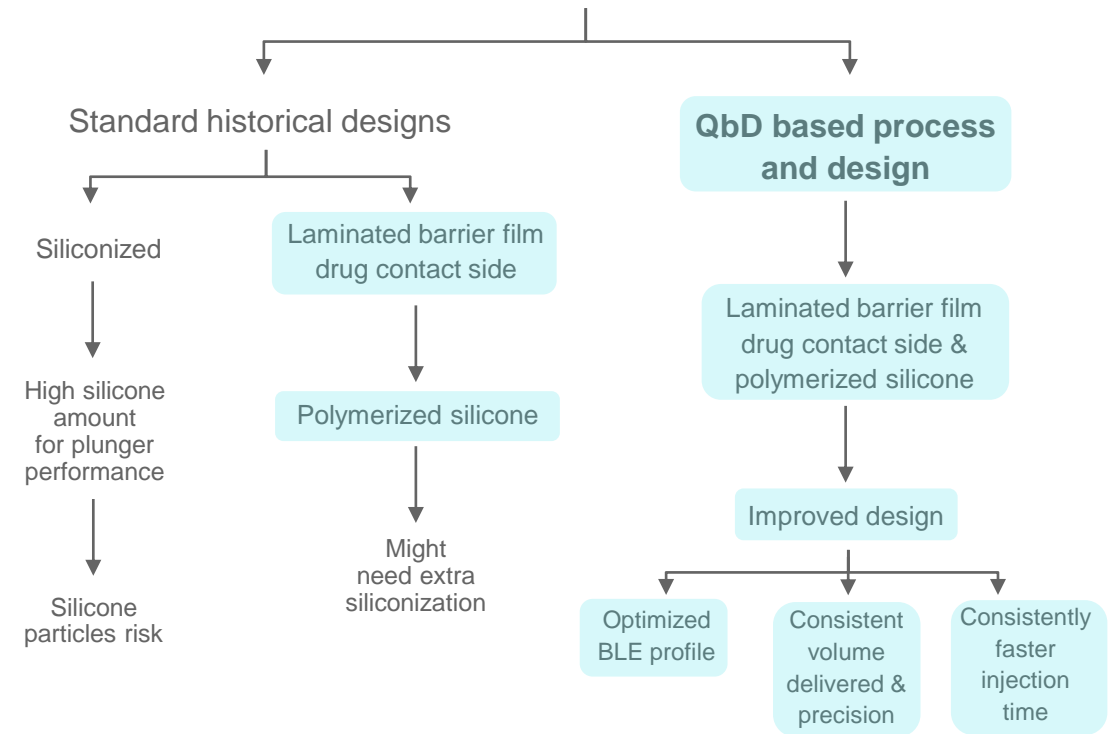


Source: West TR 2000/026 B2-Coating Quantitative Particle Analysis, West TR 2019/210 FluroTec® Products Protecting Drug Product Quality and Safety, West TR 2011/140 Impact of Steam and Gamma Processing on Elastomers, West TR 2008/129 Global West's Envision™ Process Validation Summary, West TR 2015/168 Filling Line Machinability Assessments 1-3mL NovaPure Plgr 4023/50 Gray

Decision | Plunger rubber components

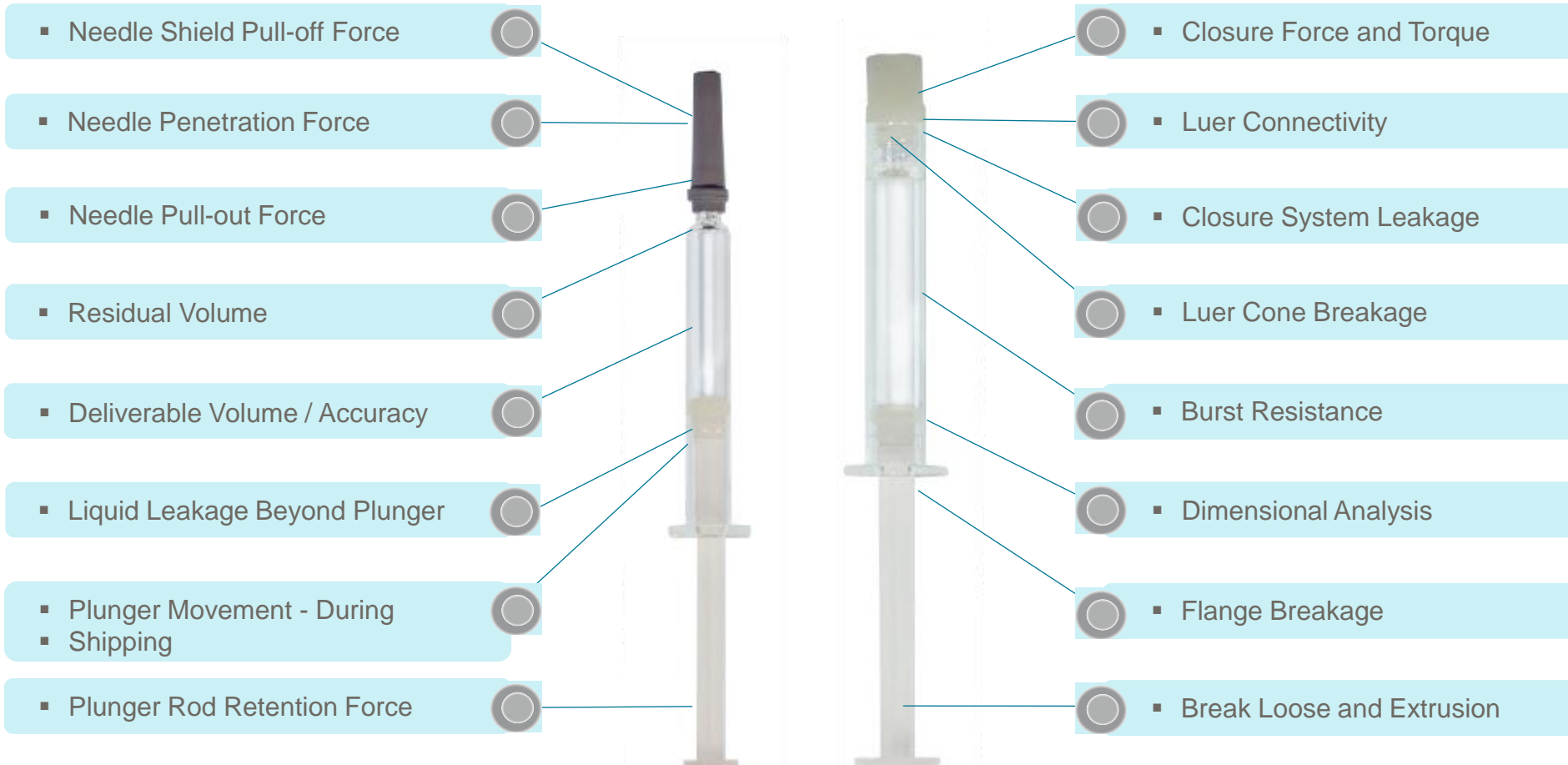


BLE = break loose and extrusion



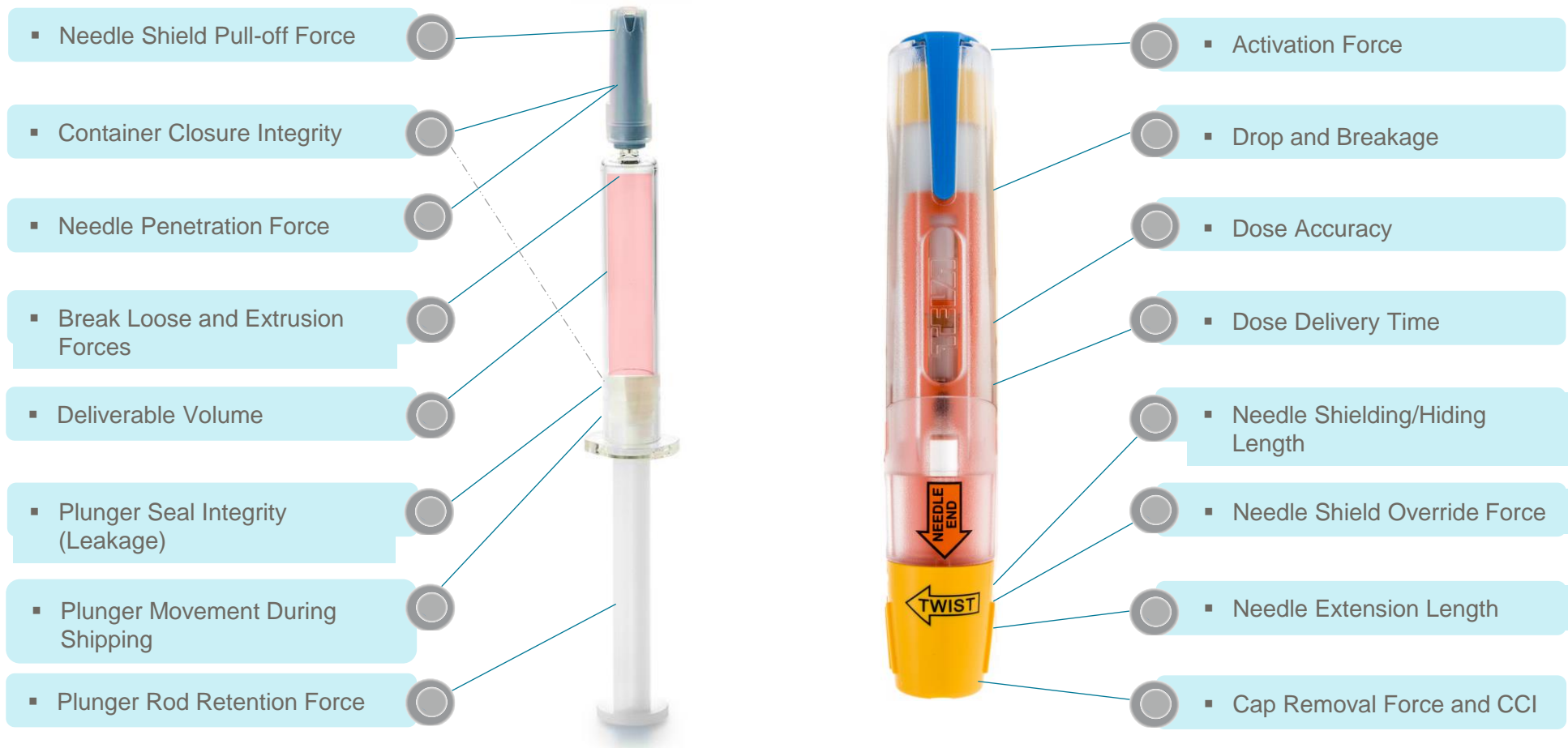
Source: West TR 2013/147 NovaPure® 1mL Long 4023/50 Gray Plunger vs. Article 2340 4023/50 Gray Plunger Break Loose and Extrusion Performance Comparison, West TR 2018/191 1mL Long NovaPure® Plunger Performance in a Model AutoInjector System, West TR 2018/198: 1-3mL NovaPure Plgr Performance in a Model Auto-Injector System

Pre-filled syringe functional performance tests



Consider all interfaces as potential failure points

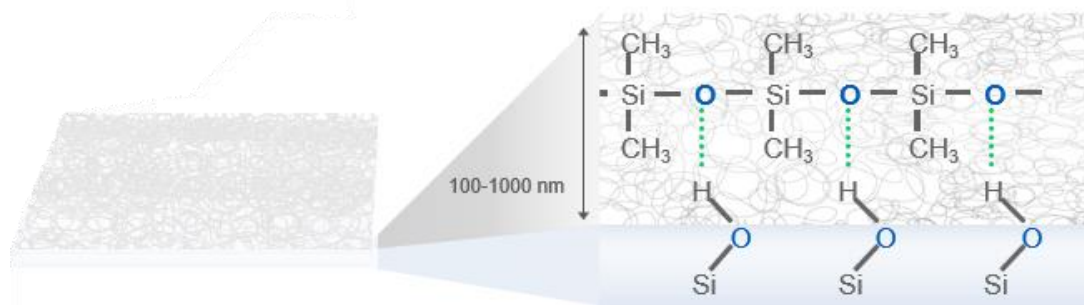
Auto-injector functional performance tests





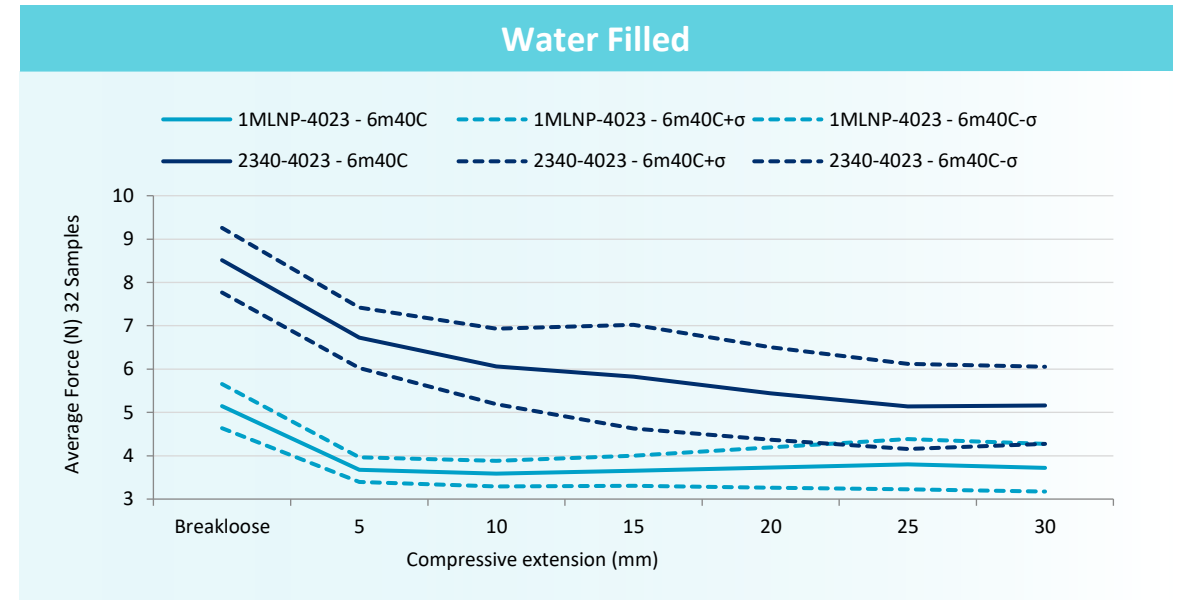
Consider all interfaces as potential failure points

Decision | sprayed-on silicone

Silicone oil is sprayed-on and adhere to the glass surface
Adhesion is reversible, leading potentially to free silicone particles in the drug depends on solvent, API, temperature..



 polydimethylsiloxanes PDMS(silicones)
 hydrogen bond



* Jones, LaToya S.; Kaufmann, Allyn; Middaugh, C. Russell, Journal of Pharmaceutical Science , Volume 94 (4) Wiley 2005
www.ondrugdelivery.com - injectabledrug delivery 2013 Formulations Focus

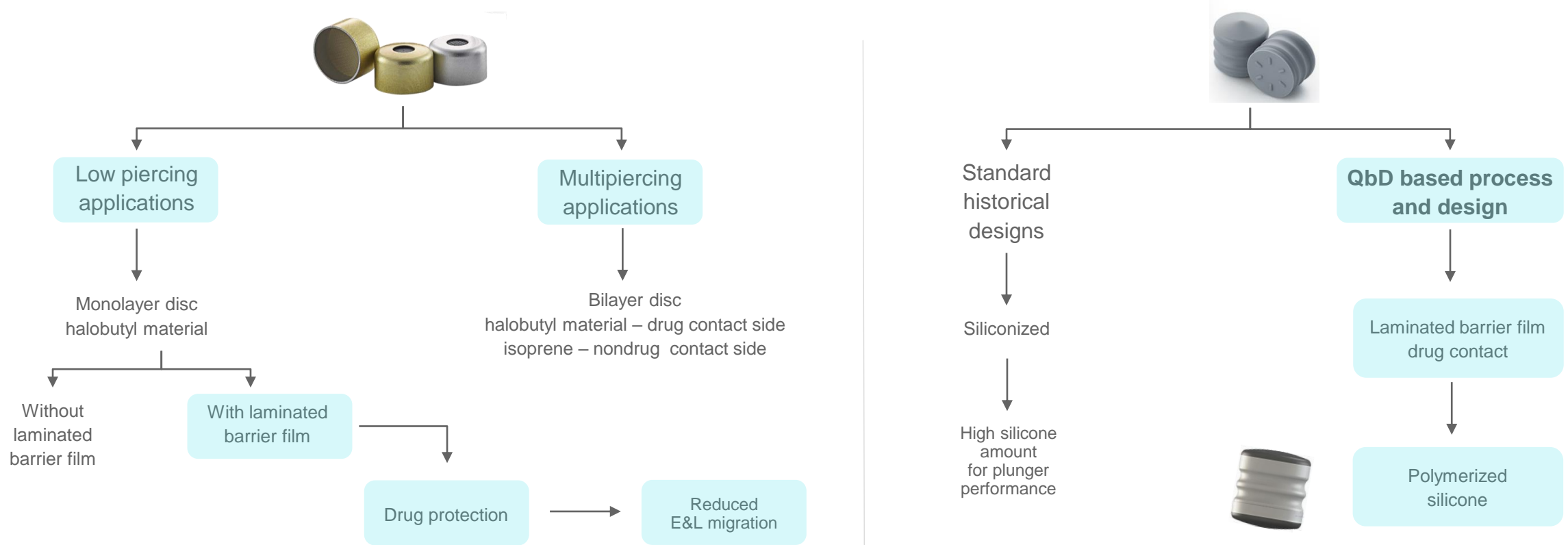
Source: West TR 2013/147 NovaPure® 1mL Long 4023/50 Gray Plunger vs. Article 2340 4023/50 Gray Plunger Break Loose and Extrusion Performance Comparison





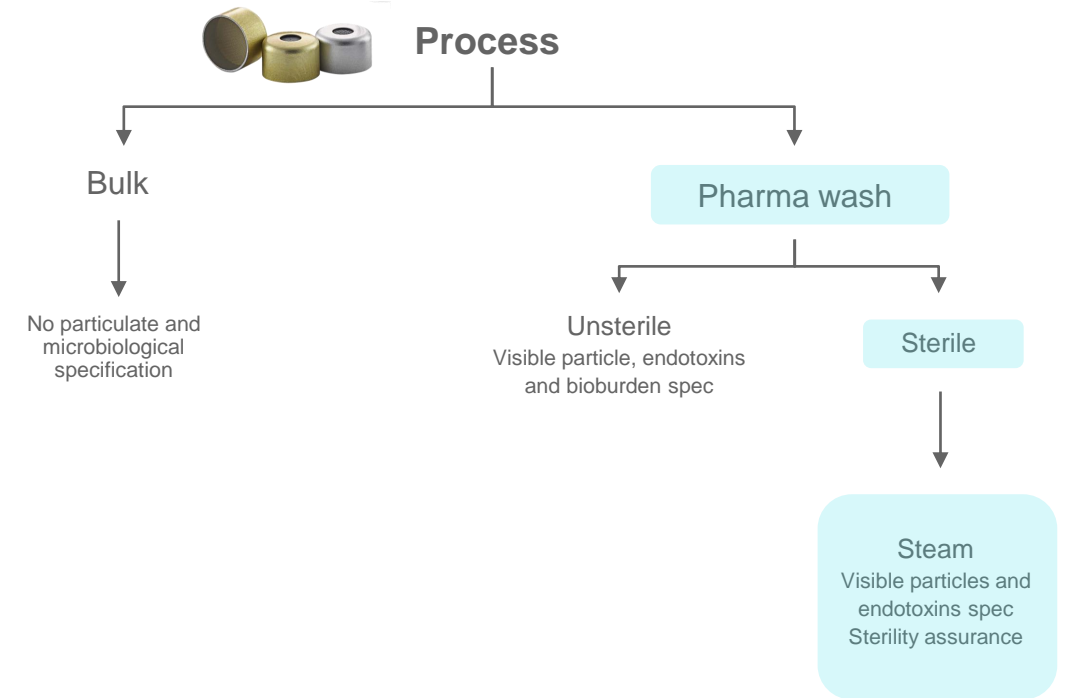
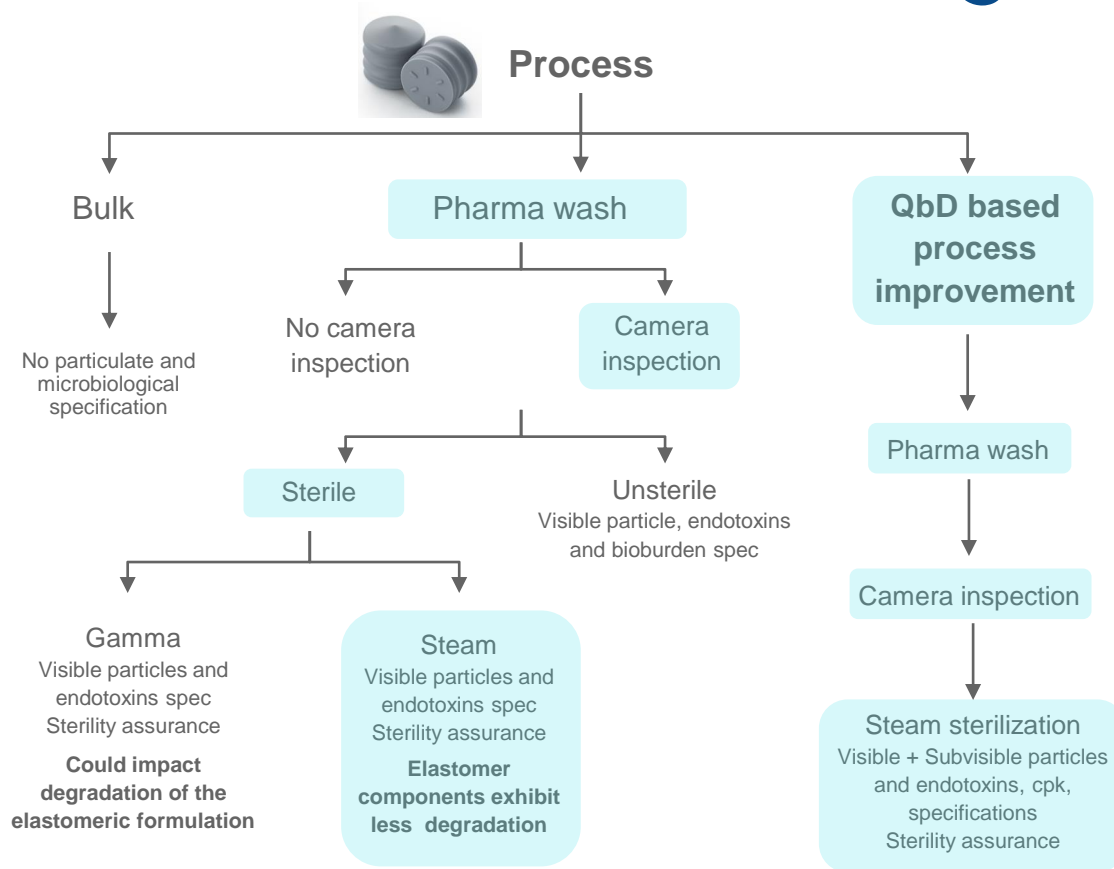
Cartridges

Decision | Cartridge rubber components



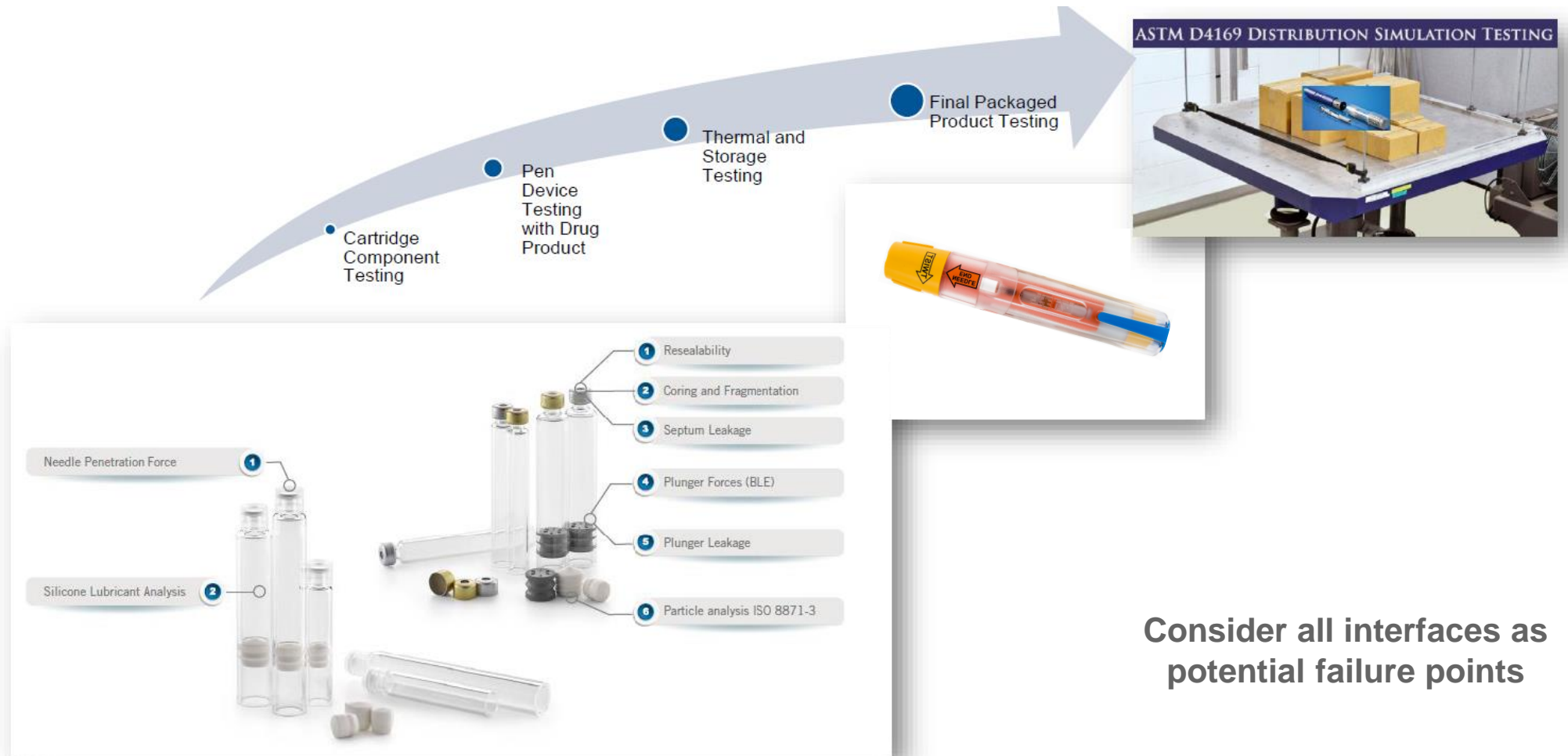
Source: West TR 2023/267 FluroTec® 1.5mL Cartridge Plunger Performance, West TR 2015/164 Westar® Ready-to-Use (RU) Cartridge Lined Seal Functional Characteristics

Decision | Cartridge rubber components



Source: West TR 2011/140 Impact of Steam and Gamma Processing on Elastomers, West TR 2008/129 Global West's Envision™ Process Validation Summary

Cartridges end-to-end performance testing

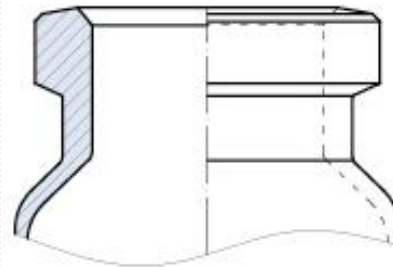


Consider all interfaces as potential failure points

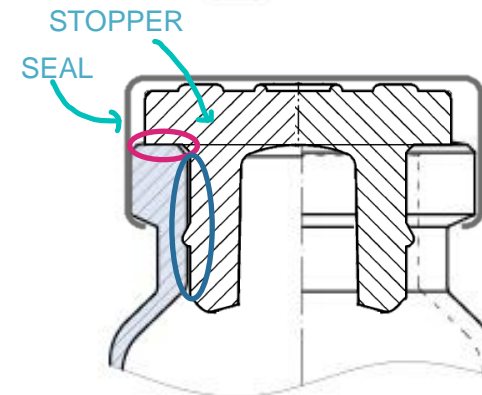
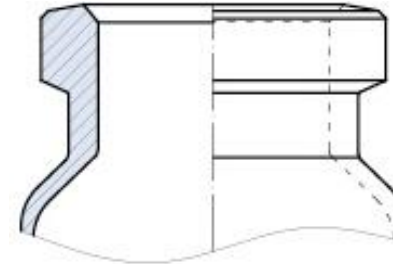
Decision | seal integrity



No Blowback 8 mm
(NBB)

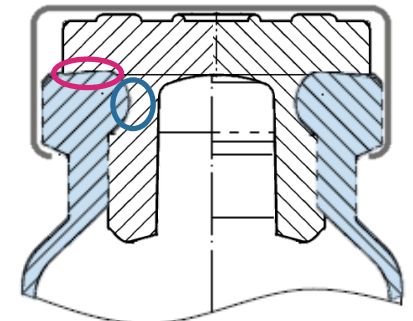
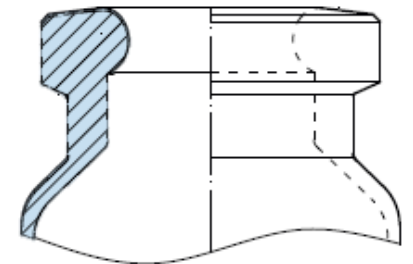


No Blowback 13 mm
(NBB)



Sealing before crimp = valve plug seal
Sealing after crimp = land seal

European Blowback
13 mm (EBB)

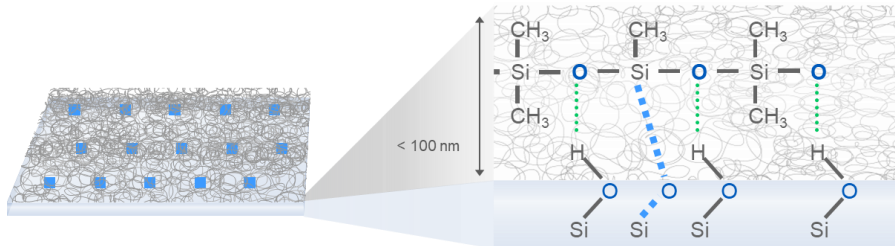


Decision | baked-on silicone

Silicone emulsion is sprayed-on and cured by heat treatment

Free silicone oil is reduced to approx. 10% compared to sprayed

Additional **covalent bond** ~20 x more stable than the hydrogen bond
(~444 kJ/mol O-Si vs. ~21 kJ/mol O-H..O)



polydimethylsiloxanes PDMS(silicones)



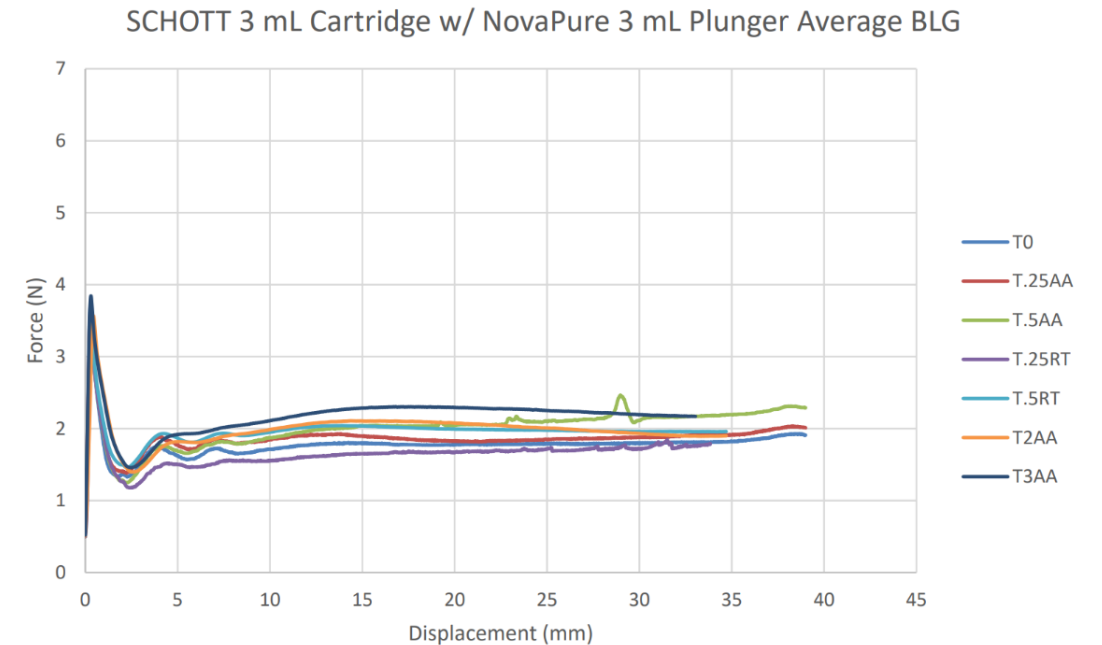
hydrogen bonding



anchor sites of PDMS



covalent bond, attaches PDMS to
glass substrate



* Jones, LaToya S.; Kaufmann, Allyn; Middaugh, C. Russell, Journal of Pharmaceutical Science , Volume 94 (4) Wiley 2005
www.ondrugdelivery.com - injectable drug delivery 2013 Formulations Focus

Source: West TR 2020/234 NovaPure® 3 mL 4023/50 Gray Plunger Performance in
SCHOTT cartriQ™ Cartridge Barrels

More to come

- Reduced extractables and leachables
- Particulate risk mitigation
- Container closure integrity and testing
- Sustainability
- Simulations / mathematical models
- Tighter legislations





Parenteral packaging components play a major role on the container closure system functionality and safety



Consider important properties e.g. E&L & CCI



Fitness for Purpose must be evaluated



Data generated must address the question being asked & risks



Leverage suppliers existing technical expertise for primary packaging selection & testing

Thank you for your attention!

