Scientific and Regulatory Expectations of the Pharma Industry

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Primary packaging manufacturers can contribute to a successful pharmaceutical product launch by their laboratory and regulatory services

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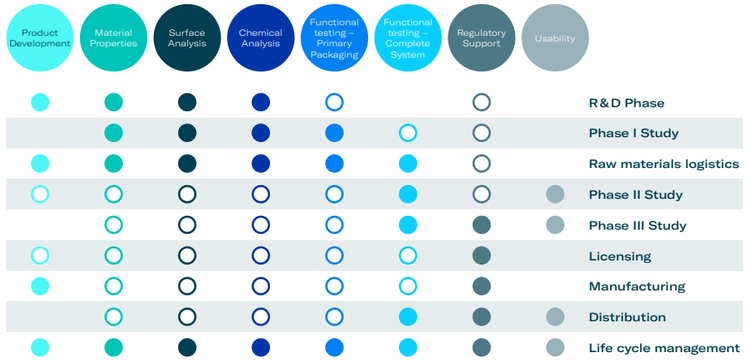
Pre-filled syringes, injectors or inhalers are developed in the format of Drug Device Combinations (DDCs). The pharmaceutical industry is challenged by new tasks especially with regard to relevant regulations. In order to fulfill complex tasks and to support pharma customers, many actions are taken to enable organizations with in-depth product knowledge, lab and testing capabilities as well as regulatory expertise by support of the new Gerresheimer Biological Solutions Group.

The key to reduce time to market of new products and to make life-cycle management easier

Gx® Biological Solutions provides integrated approach to support



Gx® Services and support on all levels of the pharma value chain

Medical Devices Regulation EU MDR

CFDA Chinese Food and Drug Administration

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

FDA

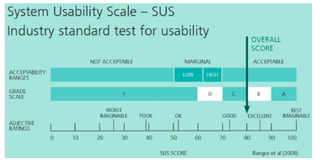
- U.S. Pharmacopoeia, current edition
- European Pharmacopoeia, current edition
- ISO 8362-1:2018, Injection Containers and Accessories
- ISO 10993-7:2008, Biological Evaluation of Medical Devices
- ISO 11135-1:2014, Sterilization of Health Care Products Package
- US FDA´ s Combination Product Guidelines 21 CFR 3.2(e)
- European Medical Device Regulation (MDR)
- Article 117, Medicinal Product Directive (Directive 2001/83/EC)
- EU's guidance on manufacturing sterile medicinal products (Annex 1)
- General Safety and Performance Requirements (GSPR) 21.1. Specifications submitted in eCTD section 3.2.P.5.1.
- ISO 15378: Primary packaging materials for medicinal products
- USP <788> Particulate Matter in Injections
- USP <71> Sterility testing conformance
- USP <85> Bacterial endotoxins
- ISO 11737-1:2018 / USP <61><62> Bioburden Testing
- ASTM F1608 and EN ISO 11607-1
- Design history file (DHF)

... and more

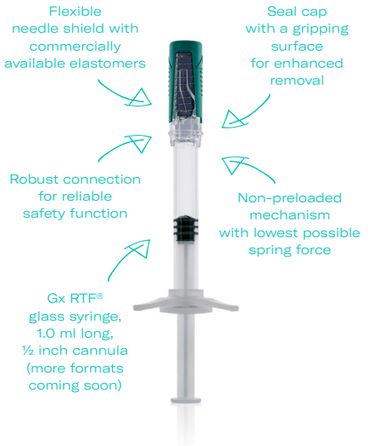
- Positive notified body opinion
- Complete pharma value chain
- Dedicated regulatory and lab services.
- Effectively support faster time-to-market for new DDCs

Safety and usability

Pre-filled syringe prevents the user from needle stick injuries. Gx Innosafe system is an integrated safety device, already assembled on the ready to fill (RTF) syringe.



Registration data on usability tests can be provided.



Dose accuracy and residual volume

Delivery volumes have been tested for 3 different syringes (1; 1,5 and 2 ml). Gx In-house data

Residual volume

Dose accuracy

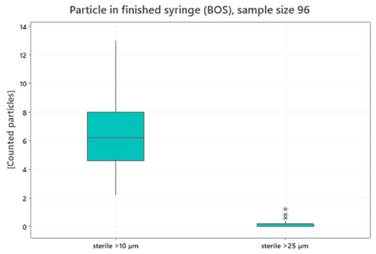
Accurate delivery of the prefilled syringe is considered as a critical aspect of the DDC safety.

Analytical laboratories can support pharma customers with tests, e.g. verifying hold-up volumes as well as delivery volumes

Particle analysis to meet high end requirements

Devices shall be designed and manufactured in such a way as to reduce the risks posed by substances or particles, that may be released from the device.

Together with pharma-companies customized solutions are developed for syringes, having lower, customer defined particle load. The patented technology of baked-on siliconization (BOS) enables high-end low particle combination products.



Particle load for 1 ml glass luerlock syringe with BOS.