# Primary Packaging for Pharmaceuticals
- Bottles, tubes, bags

# Secondary Packaging
- Labels, packaging made from cardboards, plastic, metals and laminates of all sorts

# Delivery Systems
- Syringes, transdermal patches, all sorts of dosage systems

# Active Pharmaceutical Ingredients and Finished Drug Formulations
- Traditional drug applications (small molecules) and biopharmaceuticals (large molecules)

# Single Use Systems (SUS)
- Filter systems, tubes, connectors, storage bags, seals, membranes

# Component Parts from Medical Devices
- Mostly higher risk class devices (Article IX of the EU Council Directive 93/42/EEC), Transfer Sets, Implants, prostheses (stents, joints, bone replacement material) components that are used in dialysis systems, contact lenses

# Kind of Materials
- Plastic, ceramics, elastomers, coatings, metals and alloys, varnished parts

## Tests According to International Standards
- Physico-chemical testing according compendium monographs
- Ph.Eur 3.X and 3.2, USP <661>X, JP 7 and customized methods
- Organic and inorganic residues, ICH Q3

## Extractables & Leachables Assessments for Finished Packaging
- EMA, US-FDA, USP <1663>, <1664>; recommendations of PQR
- Sound scientific research Leachables-screening studies
- Migrations/simulated use studies
- Leachables shelf life studies (GMP/cGMP studies)

## Extractables & Leachables Assessments for Single Use Systems (SUS)
- EMA, US-FDA, USP <665>, <1665>; current recommendations of ASTM, ISPE, BPSA, BPOG, PDA can be taken in account

## Chemical Characterization
- Quantitative and qualitative determinations of plastic additives and related substances (impurities/breakdowns)
- Chemical characterization studies according to ISO 10993
- Biocompatibility studies inVivo, inVitro on special request) for medical devices and system-components according to ISO 10993, USP <87> and <88>
- Aging studies under accelerated conditions according to ASTM F 1980-07

## Additional Services
- Impurity profiling in any starter material for pharmaceutical use, solutions, bulk or others
- Particle identification and particle distribution
- Cleanness of surfaces
- Material failures and damage analysis by analytical methods

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