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## Reference standards for quality control

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The generic terminology reference standard is used to cover the reference substances, reference preparations and reference spectra. The Reference Standards (RS) are used to achieve adequate quality control of substances for pharmaceutical use and pharmaceutical preparations. The reference standards are never intended for human therapeutic use, so patient safety is not directly impacted. The RS are elaborated according to suitable procedures. Appropriate tests for qualification are performed to ensure they are fit for the intended purpose. The uses of RS include the following:

- Quantitative use in assay for Drug Substances, Drug Products, limits tests.
- Qualitative use for system suitability tests (SST), identification, chromatographic peak markers, etc.
- Method-specific uses: calibration and verification measurements, melting point, dissolution tests, etc.

Depending on the intended use and the procedures for qualification, the RS are classified as: Primary Standards (PS), Secondary Standards (SS) and Reference Materials (RM). The official Reference Standards are elaborated and distributed by the official organizations such as: European Pharmacopeia (EDQM), United State Pharmacopeia (USP) and World Health Organization (WHO). They are Primary Standards and can be used for establishing Secondary Standards. The traceability and the equivalency of SS against PS must be demonstrated.

Within UCB Pharma, the RS are globally managed and coordinated by Quality Control Corporate, for both New Chemical Entities (NCE) and New Biological Preparations. Appropriate procedures are defined for qualification and stock management. The samples from the Central Stock are distributed to different destinations (outsourcing sites, customers, authorities, etc.) respecting very challenging storage conditions (i.e. -60°C in summer time). For any Quality Control department, the Reference Standards is one of the key factors in assuring the quality of medicines for patients during GMP activities.

## Biography

Cornelia Horoiu holds a Master in Quality Control and Quality Management from Bordeaux II University, France and a BS in Chemistry from Galati University, Romania. Working for more than 9 years in Quality Control for UCB Pharma, she is currently in charge of Global Management of the Reference Standards for all UCB products. During her tenure with USB, she also covered product releases, dissolution tests, specifications for product release and stability.

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