

## Dissolution: Applications, regulations and critical control points



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### **Applications:**

- Quality Control (Pharma, Food and Chemical Industry)
- R&D: Method Development, Properties of the API, Design of the Drug Product (Galenics), IVIVC
- Comparative Studies such as Biowaiver and Stability Measurements

### **Critical Control Points:**

- Mechanical Calibration
- Validation, SOPs
- Media, Environment (Vibration), Vessel Quality, Analytical Methods, Education Level of the Staff

### **News: International Regulations:**

- EP, USP, US FDA, ASTM, WHO, CP and other local Pharmacopoeia, USP 1092

Dr. Dirk Beilke has studied Chemistry at the University of Frankfurt and received his PhD in the department of Biophysical Chemistry. After his University career he worked for Merck KGaA Germany. He joined Pharma Test AG in the year 2004 and was responsible for the development of the Pharma Test dissolution product range and the Asian Market. Nowadays he is still focusing on the dissolution instrumentation as well as on spectroscopic PAT solutions. New dissolution apparatus such as the dispersion releaser are currently developed to allow pharmaceutical and chemical quality control departments to test the release rate of nanomedicine, microparticles and semi-solid dosage forms.

Pharma Test AG is a company located in Hainburg nearby Frankfurt /Germany. It was founded 1979 and is nowadays one of the world leaders in the dissolution and galenical drug test equipment market. In addition to Dissolution Testers, Pharma Test AG is also offering Powder Testers, Tablet Hardness Testers, Friability Testers, Disintegration Testers, Blister Leakage Testers and Media Preparations Systems. The Pharma Test Group also focusses on PAT technologies and provides a wide range of spectroscopic in-line and at-line solutions.