NIRS in Quality Control - Regulatory Aspects

Federal Institute for Drugs and Medical Devices, Bonn
Dr. Martin Diller
Regulatory documents

• Near Infrared Spectrophotometry
  European Pharmacopoeia 4.05, 2.2.40

• Note for Guidance on the Use of Near Infrared Spectroscopy by the Pharmaceutical Industry and the Data Requirements for new Submissions and Variations CPMP/QWP/3309/01, Aug 2003

• Note for Guidance
  – on Validation of Analytical Procedures: Methodology (CPMP/ICH/281/95)
  – on Validation of Analytical Methods: Definitions and Terminology (CPMP/ICH/381/95)
Regulatory status

(CTMP/QWP/3309/01)

well established method

no limitation to herbal substances

NIRS

differs from conventional analysis

validated reference method(s)

alternate method „only“

limited experience

Note for Guidance

CTMP/QWP/3309/01
Qualitative Methods

Spectra Library

Identification
Qualification

1. Wavelength Correlation
2. Maximal Wavelength Distance
   Others should be justified!
Quantitative Methods

**Unknown NIRS spectrum**

Identification/Qualification

Equation

**Predicted value**

**NIRS spectra**

Validation set

Calibration set

Database

NIRS spectra

**Validated reference values**

Regression
Change control

Changes

effect on NIRS method

affect performance

Re - Validation

Variations application
Conclusion

• Note for Guidance CPMP/QWP/3309/01
  – basis for developing and assessing NIRS methods
  – data for the quality part have to be in accordance with the requirements
  – differences should be justified scientifically

• Developing NIRS methods for herbal drug preparations etc. may be more demanding than for pure chemical substances