

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


(CPMP/QWP/3309/01)

well established method

no limitation to
herbal substances



Note for Guidance
CPMP/QWP/3309/01

 differs from
conventional analysis

NIRS

limited experience

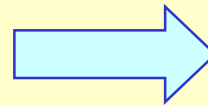
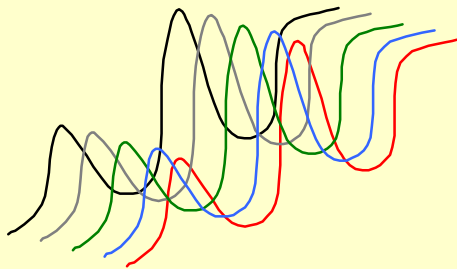
validated reference
method(s)



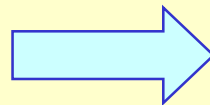
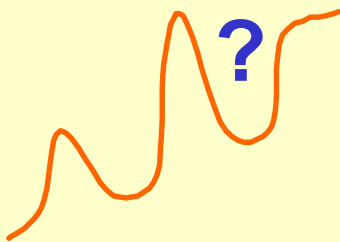
alternate method
„only“

Qualitative Methods

Spectra Library



**Identification
Qualification**



1. **Wavelength Correlation**
 2. **Maximal Wavelength Distance**
- Others should be justified !

Quantitative Methods

Unknown NIRS spectrum



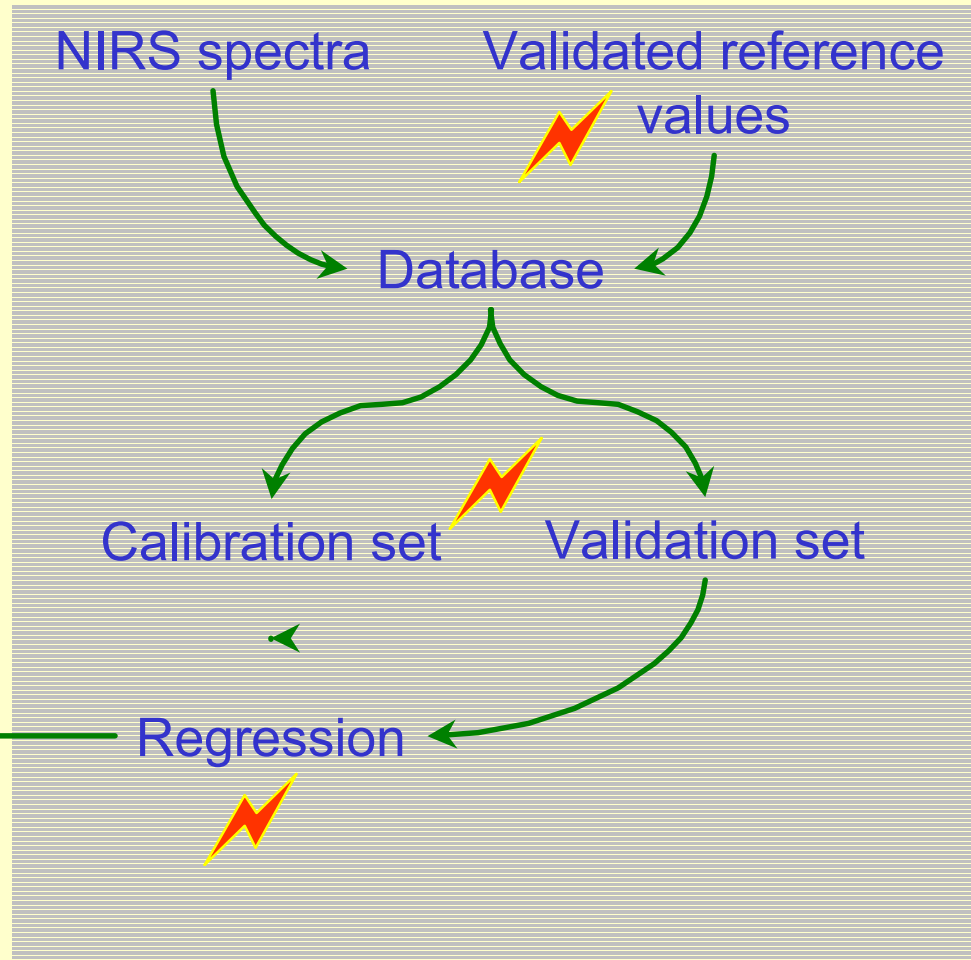
Identification/Qualification



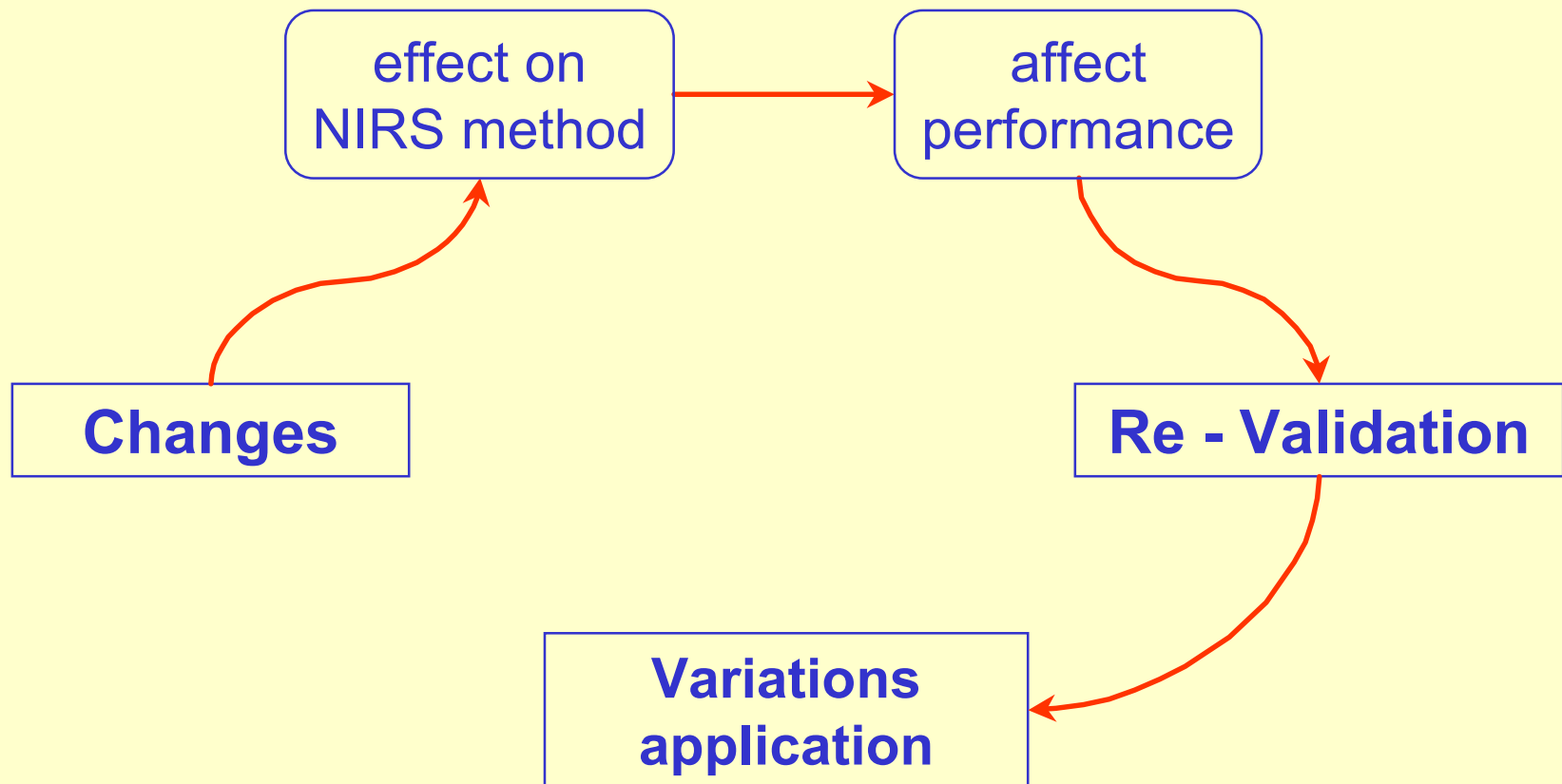
Equation



Predicted value



Change control



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