Methods in Pharmaceutical Analysis, Regulatory, Validation and Practical Aspects

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FACULTÉ DES SCIENCES
SECTION DES SCIENCES PHARMACEUTIQUES

Ecole de Pharmacie
EPGL
Genève - Lausanne

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Outline

- Day 1:

- Introduction- Presentation

- Titrimetric methods
- Spectroscopic methods

- Documentation and regulatory bodies Pharmacopeias, ICH guidelines, ISO 17025
- Objectives of validation: Validation and Quality Assurances (QA) – traceability
- Terminology and definitions

- Day 2:

- Introduction to separation techniques
- Thin-layer and gas chromatography

- Practical guidelines for method validation. Methods for quantitative analysis

Outline

- Day 3:

- Liquid chromatography and practical aspects

- Statistical aspects for pharmaceutical analysis
- Experimental design and data treatment

- Day 4:

- Capillary electrophoresis and alternative approaches

- Construction of an Excel file for target method validation

- Questions and final discussion

Pharmaceutical/biomedical analysis fields

pharmaceutical and biomedical analysis

chemical/biological *characterization (raw material, end-product)*

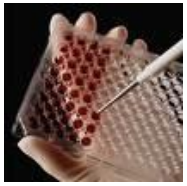
pharmacy

e.g. impurity, enantiomer, isoform profiles, stability tests, quality control

forensic toxicology

e.g. death investigation, human performance, workplace drug testing, doping control

charactezization of ***exogenous*** *cpds in* ***biological*** *matrices*



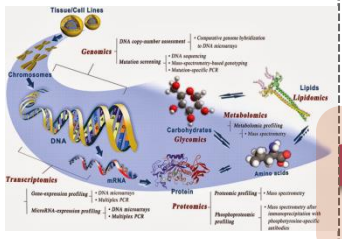
clinical toxicology

e.g. therapeutic drug monitoring

clinical biochemistry

e.g. enzyme activities, renal/liver functions, cardiac markers

characterization of ***endogenous*** *cpds in* ***biological*** *matrices*



omics

e.g. metabolomics, proteomics

Analytical Sciences

Prof.
J.-L. Veuthey

Pharmaceutical Analysis

Separation sciences: Fundamentals

Analysis of :
- Drugs
- Drugs of abuse
- Doping substances
- Biomolecules

New methodologies ;
Green Chemistry, etc.

Analytical Sciences

Complex matrices
Toxicological analysis
Metabolism
Metabolomics

Hyphenated methods to MS
Multivariate Data Analysis

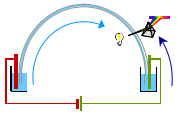
Prof.
S. Rudaz

Biomedical Analysis

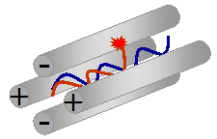
Analytical sciences: Application fields

(UHP)LC – SFC
Fast analysis
Fundamental

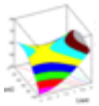
Miniaturisation and CE
Substandard Medicines
Counterfeit drugs

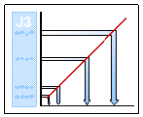


MS Detection
and alternatives



Chemometrics
Validation



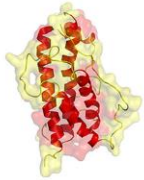


Metabolomics

Metabolism

Biological Fluids
Sample preparation

Peptides
Proteins
mAbs



Toxicology
Pre-clinical analysis

Prototype / Counterfeit Medicines

A counterfeit medicine is a medicine that is deliberately and fraudulently mislabeled with respect to identity and/or source.

Counterfeits may include products

(i) with correct ingredients/components,
(ii) with wrong ingredients/components,
(iii) without active ingredients,
(iv) with incorrect amounts of active ingredients
(v) with fake packaging.

Drug quality control

UNIVERSITÉ DE GENÈVE


HUG

Trophée de l'Innovation des HUG 2010

4ème Journée de l'Innovation

Prof. Pascal Bonnabry

HUG Hôpitaux Universitaires de Genève

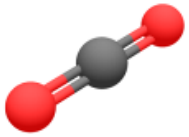
Hes·so FRIBOURG FREIBURG
Haute Ecole Spécialisée de Suisse occidentale

Prof. J-L. Veuthey / Competences

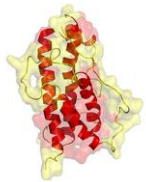
Jean-Luc Veuthey is Full Professor since 1992. Authors of more than 300 publications in the field of analytical chemistry, he was selected in 2013, 2015 and 2017 among the top 100 most influent leaders in analytical sciences. He was president of the School of pharmacy (1998-2004), vice-Dean of the faculty of sciences (2004-2010) and vice-rector of the University of Geneva (2011-2015).

Fast analysis
Fundamental

Alternative in separation sciences



Peptides
Proteins
mAbs

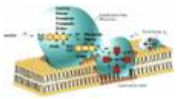


Prof. S Rudaz / Competences

Associate Professor since 2012, he's member of the management Board of the Swiss Centre for Applied Human Toxicology (SCAHT) Fundation, vice-président of the Competence Center in Chemical and Toxicological Analysis (ccCTA) and vice-president of the French Association of Separation Sciences (AFSEP). He published numerous scientific papers (>250) or book chapters (>10) in analytics, mainly focused on separation sciences, bioanalysis, data treatment and metabolomics.

Complex matrices
Biological Fluids

Metabolism
Toxicology
Pre-clinical analysis
Metabolomics



Chemometrics
Validation