ONE-STOP-SHOP SOLUTION FOR IMPURITY ISSUES

Impurity profiling in drug development processes

Impurity related deviation management in routine manufacturing

RD&C's IMPURITY PROFILING acc. to ICH, EMA and FDA guidelines

Impurities, degradation products, elemental impurities

Evalution of safety aspects

In silico (Q)SAR toxicity assessment

Proposal of regulatory compliant argumentation

Integral analysis of the entire production process

Selection and/ or cooperation with relevant CROs

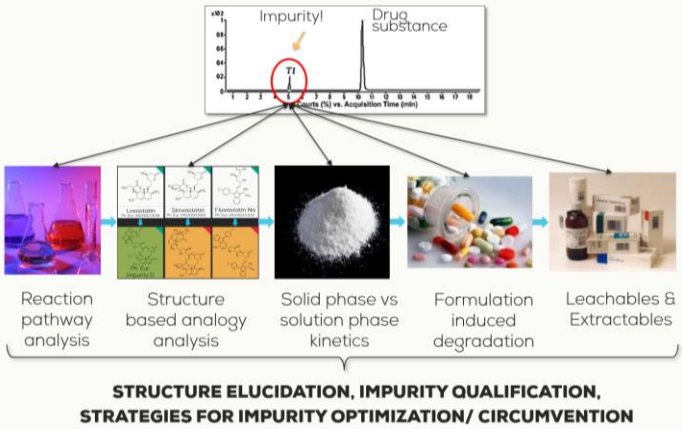
Development and life-cycle management of control strategies

Planning, management and evaluation of analytical procedures

Calculation of Permitted Daily Exposure (PDE) and concentration limits

Classification, identification and qualification; assessment, reporting and control

Systemic Impurity Analysis



(Potential) Mutagenic impurities

Identification and classification

In silico (Q)SAR toxicologic assessment

Risk assessment

Integration of Threshold of toxicological concern (TTC) concept

Development and implementation of control strategies

RD&C Research, Development & Consulting GmbH

Dr. Helmut Buschmann | Dr. Norbert Handler

Neuwaldegger Str. 35/2/3; 1170 Vienna; AUSTRIA; phone: +43 664 8293350

Ludwigsallee 21; 52062 Aachen; GERMANY; phone +49 241 92 04 08 28

office@rdc-concepts.com; www.rdc-concepts.com