

Dear customers and friends of Chromicent,

Our autumn was all about events, trade fairs and conferences. It is always a particular pleasure for us to present our work to a wide audience, and even more so when we are met with such enthusiasm.

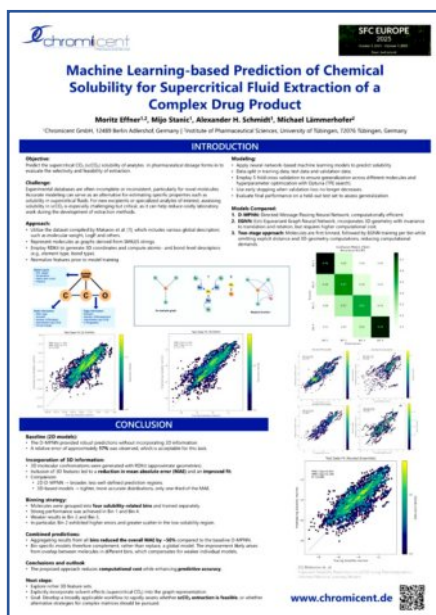
Modern methods require modern thinking: QbD enables it, SFC delivers it



Under this topic, Chromicent was represented with its own stand at this year's **SFC Congress in Basel**.

In his presentation, our nitrosamine specialist Dr Andreas Zappe introduced our **'One for all' platform method**, which uses SFC-MS/MS to detect a wide range of nitrosamines, naturally in accordance with GMP.

The interest that followed the presentation clearly showed how central the topic of **nitrosamine analysis** continues to be. With its platform method, Chromicent is making an important contribution to **drug safety** and the prevention of **drug shortages**.



Moritz Effner won the Best Poster Award with:

'Machine learning-based prediction of chemical solubility for extraction with supercritical fluids'.

Data-driven models for sample preparation are both innovative and forward-looking; they reduce the amount of experimentation required and accelerate and optimise the development of analytical methods.

Our doctoral student Adrian Schust demonstrated the diversity of SFC with his poster 'Between Essential and Toxic' on the topic of **heavy metals and SFC**.

We would like to thank everyone for their interest, the friendly encounters and the lively exchange of ideas.





SFC
Supercritical Fluid
Chromatography
in a GMP Environment

**Pharmaceutical Services &
Analytical Excellence**

**MLCM - Method LifeCycle
Management**

Stage 1: ICH Q14 – AQBd
Stage 2: ICH Q2 Validation
Stage 3: ICH Q1 Stability Testing

Our Expertise
API & Drugs
Nitrosamine Analysis
Extractables & Leachables
Chiral SFC
Polymer Analysis
and more ...



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ICH Q14 – Development of analytical methods

In September, the Concept Heidelberg event

'ICH Q14 – Development of Analytical Methods'

took place in Adlershof, as every year. A detailed tour of our laboratories and a joint dinner are already a firm tradition and always provide an opportunity for intensive exchange.

The presentations by Chromicent focused on **Quality by Design** and **ICH Q14, orthogonal analysis options with SFC** and **robustness testing**.

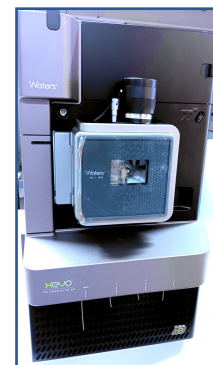
WATERS Separation Days

We continued our close collaboration with Waters, including presenting at the Waters Separation Days in Dortmund with the lecture:

'SFC – The forgotten technology and untapped opportunities'.

In particular, we presented applications that were developed and established at Chromicent. Keywords: **ICH Q14, nitrosamines, extractables and leachables, chiral SFC, peptides and heavy metal analysis**.

Would you like to know more? [Please contact us.](#)



Furthermore, we welcome the **Waters Xevo TQ Absolute** as our 'new employee'. **Precision, reliability and excellence** in modern analytics – that's what we stand for, and that's what the Waters Xevo TQ Absolute stands for too.

Prospect

Dr Alexander H. Schmidt is currently working on a **case study on the new ICH Q1 guideline – Stability testing**.



The **draft of the ICH Q1 Guideline published in June is intended to replace the previous Q1A–Q1F and Q5C guidelines**, which concern stability testing for active ingredients and finished medicinal products. The new guideline aims to:

- close existing gaps
- integrate current scientific findings
- emphasise risk- and science-based principles

Chromicent **already develops and evaluates stability protocols according to these standards** and will demonstrate the **advantages and potential** of this strategy in a **practical manner** in the planned case study by Dr Alexander H. Schmidt.

Look forward to it – [or simply contact us.](#)