10TH ANNIVERSARY

chromicent Pharmaceutical Services

EVENTS

STARTING BUSINESS

2014

On **1 March 2014** the newly founded Chromicent GmbH moved into their first laboratory and office building in the IGZ in Berlin-Adlershof.

CHROMICENT IS GMP-CERTIFIED SINCE 2015

During the inspections by the local drug authority in accordance with § 64 of the German Medicinal Products Act, Chromicent's proactive approach was always explicitly appreciated.

EVENTS

Events, conferences and seminars have always been part of Chromicent's concept.

We look back with pleasure on a variety of interesting meetings and discussions.

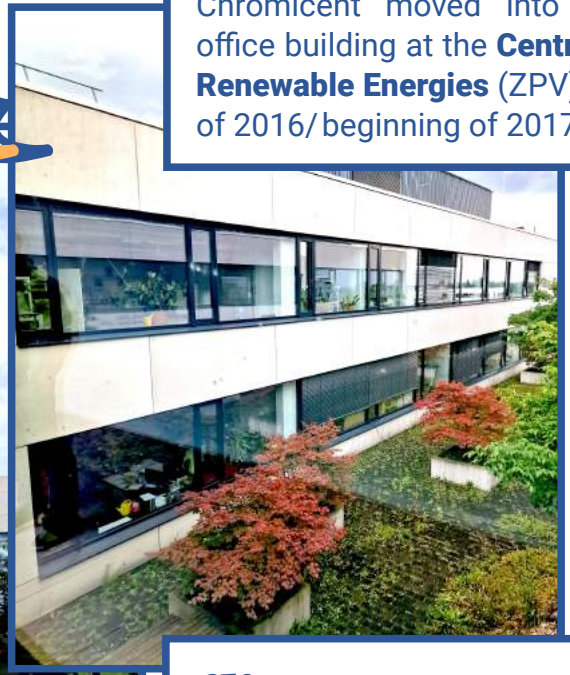
2015

CERTIFIED GMP CERTIFIED

2017

RELOCATION

Chromicent moved into its current laboratory office building at the **Centre for Photovoltaics and Renewable Energies** (ZPV) in Adlershof at the end of 2016/ beginning of 2017.



VALSARTAN/NITROSAMINES

In 2019 the nitrosamine crisis began with impurities in valsartan.
Chromicent's **SFC-MS/MS method** laid the foundation for our successful work.

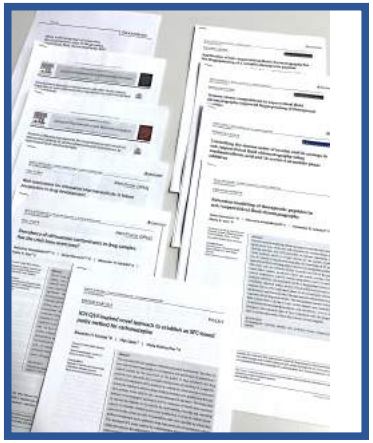
2019

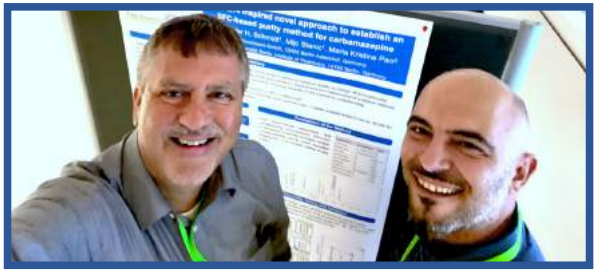
SFC

SFC

From the first days of Chromicent, SFC has been part of our laboratory equipment.

Today, we can proudly present:
10 publications in reputable journals on method development using SFC, ***4*** of them on nitrosamines and another ***4*** on peptides.



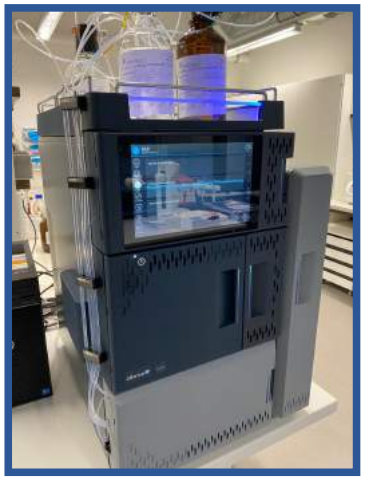


FROM 4 TO 23

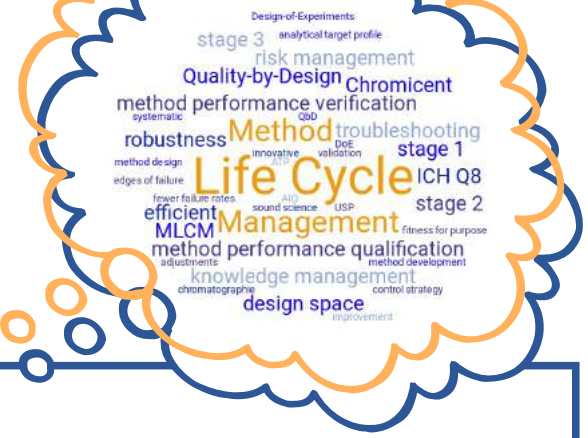
CHROMATOGRAPHIC INSTRUMENTS

The Chromicent adventure began with just **4** chromatographic instruments and today we have **23** systems including **HPLC & UPLC, IC, SFC, GC and three MS.**

2021



MLCM



MLCM & ICH Q14

Chromicent has developed its Quality by Design approach into a comprehensive Method LifeCycle Management system. We are particularly pleased **that the final ICH Q14 has been published on our 10th anniversary** and is supporting and validating our work.

DETECTORS

In 2021, we have once again upgraded in the detection segment and now have:
UV/PDA, FL, ELSD, CAD, RI, MSD, TQD, ECD and conductivity detectors.

SCIENCE + COMPLIANCE

10 & 24 & 140

Chromicent is **10 years old, 24 permanent employees** enrich our team and we are **pleased to have more than 140 customers** in the pharmaceutical industry. Our customers are from **Germany, the EU, the UK, the USA and Latin America** - and we would like to thank them for their great cooperation.
Here's to the next 10 years!

TWO POLAR OPPOSITES - ONE IDEA

Chromicent never wanted to be a run-of-the-mill contract laboratory - from the very beginning, our motivation was to **connect research, innovation and development with the necessities of regulations and GMP standards.**
We, Dr. Alexander H. Schmidt and Mijo Stanic, are fundamentally different as founders and therefore the perfect duo - and this is mirrored in our team, in the cooperation with our partners and in the satisfaction of our customers.

2024

LIMS

Brand new and red hot: **Chromicent's LIMS** (Laboratory Information Management System).

Data integrity and efficiency should not contradict each other - with the iLES system from iVention, we have opted for the best-practice solution.

VOICES ON CHROMICENT

Chromicent doesn't just **provide data -** it provides **solutions!**
(say the customers)

Great variation, lots of different tasks and many new challenges.
(say the employees)

It's truly impressive to witness the application of QbD principles in the initial phases of SFC method development for biopharmaceuticals.
(Comment on LinkedIn)

I appreciate Chromicent because it encourages creative work.

It also offers me the flexible working conditions that I wish for as a new father.
(say the employees)

This proven QbD approach should become the new standard in QC labs in life sciences. (comment on LinkedIn).

From my perspective as a Lead & Performance Auditor, Chromicent is in a league of its own in analytical method robustness with its lifecycle approach according to ICH Q14.
(Comment on LinkedIn)

SERVICE **PORTFOLIO**

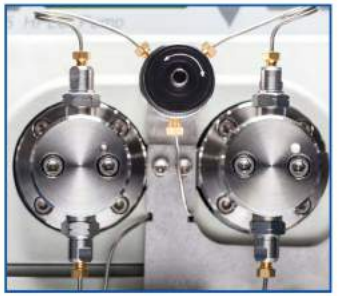
chromicent Pharmaceutical Services

Chromatographic method development & pharmaceutical analysis

Method Lifecycle Management (MLCM)

- Method development in a QbD framework (Stage 1)
- Robustness testing (Stage 1&2)
- Validation studies (Stage 2)
- Stress, stability and release testing (Stage 3)
- Troubleshooting of existing methods (in all Stages)
- Consulting and Training

certified GMP certified



Analytical capabitities

- Chromatographic systems controlled by Empower 3 (Waters)
  - HPLC (Waters Alliance)
  - UPLC (Waters Acquity)
  - UHPLC (Waters Acquity ARC), bio-inert
  - SFC (Waters Acquity UPC²)
  - IC and GC
- Comprehensive sample preparation equipment
- Pharmaceutical Technology equipment
  - Incl. Dissolution tester
  - sub-visible particle (SVP) analyzer
- Stability and Photo-stability chambers

Detection capabitities

- Photo diode array UV detection (PDA)
- Fluorescence detection (FLD)
- Refractive index detection (RID)
- Evaporative light scattering (ELSD)
- Single-Mass detection (QDa)
- Tandem-Mass detection (TQD) with ESI and APCI ion source
- Charged-Aerosol detection (CAD)
- Chemiluminescence nitrogen (CLND)
- Conductivity detection
- Electrochemical detection (ECD)

Impurity profiling

- Nitrosamine screening using our validated and published SFC-MS/MS method
- Nitrosamine detection using LC-MS/MS with APCI ion source
- Extractables and leachables studies
- Stress testing with mass balance consideration
- Photo stability testing
- ICH short- and long-term stability studies