- SEC technology at Chromicent -
- Nitrosamines -
- Accelerated drug development: our contribution to coping with the "Corona Crisis" -
- Events & Webinars -

Dear customers and friends of Chromicent,

for us, the time of lockdown wasn't a time of standstill. We did our utmost to remain as committed to our customers and partners as usual, to provide our employees in the laboratories and offices with a safe working environment, and to use the newly available free space to implement new ideas.

We are pleased to share our news from Chromicent with you and wish you a pleasant summer. Stay healthy!

Mijo Stanic and Dr. Alexander H. Schmidt
CEO Chromicent GmbH

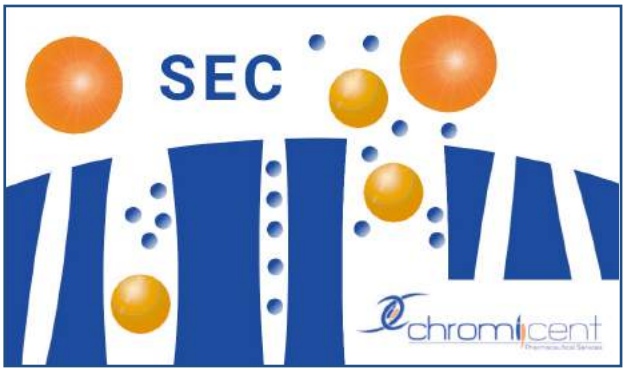
Nitrosamines

Nitrosamines remain a crucial issue in the field of pharmaceutical safety. The Waters Corp. webinar **"Analysis of nitrosamines in APIs by LC/MS: How to face all challenges?"**, led by Arjan Timmerman (Business Development Core Market), focused on the various analytical methods including **Chromicent's method allowing the separation and detection of fourteen different nitrosamines in APIs, excipients and medical products**. Arjan Timmerman emphasized that thanks to **Method LifeCycle Management**, this method meets the current and future requirements of the EMA.

For further information, please refer to our publication - or simply contact us. We are happy to support you.

Size Exclusion Chromatography (SEC)

Chromicent has enhanced its portfolio with size exchange chromatography (SEC). This chromatographic method enables us to separate molecules in solution by **size** (hydrodynamic volume) and to identify their **relative molecular weight**. The use of SEC in our laboratory routine serves the characterization of proteins, synthetic polymers and natural polymers, such as polysaccharides.



The ability to analyze multimers (dimers, trimers, polymers) particularly supports our work in the field of **impurities of ingredients**, e.g. in cases where separation with classical RP-chromatography is not sufficiently successful, or in the highly sensible and topical field of **extractables and leachables** in drugs or their packaging.

Another important keyword is: **bioanalytics**. Being able to detect **macromolecules** – i.e. proteins, carbohydrates and lipids, but also DNA and RNA – and potential changes to them is another issue of the future. An issue Chromicent is prepared for. We keep you updated.

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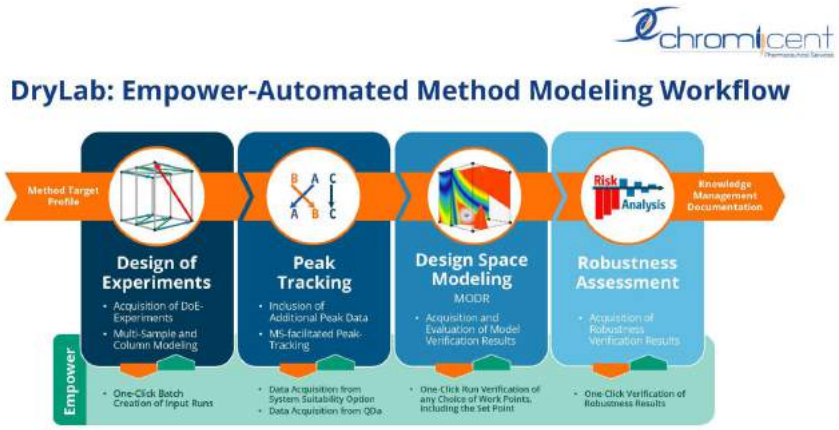
Webinars and Events

In order to guarantee our customers and partners continuous access to the latest developments in the field of analytical method development, Chromicent has increased its participation in digital events in recent months.

1 Our **presentation for the Food & Environmental Meeting** of Waters Corp. on the **determination of pyrrolizidine alkaloids in food** is available on request.

2 The webinar on:
"Analytical design space modeling in accordance with ICH Q12 and proposed Q14: Using a novel approach for in silico method development and robustness assessment" is available on demand. Please follow this LINK.



The webinar clearly demonstrate how automated AQbD modeling can be used as a strategic approach and how system-wide implementation using two established software packages for method modeling enables **seamless automation of the analytical Quality by Design approach**.
Further information can be found on our website.

ICH Q2/Q14 Analytical Procedure Life Cycle Management
From development to continued verification
16.-17. September 2020 | Berlin

The Chromicent is pleased to present a lecture with the topic :

3 The conference of the European Compliance Agency (ECA) will offer you a comprehensive overview of the new ICH Quality Guideline Q14 for Analytical Method Development and the revised Guideline Q2 for Validation of Analytical Methods. For further information please follow this LINK.

"How Software Tools can Support QbD Method Development".
Keywords: Quality-by-Design, DoE as efficient and fast tool for method development, Fusion QbD®, DryLab®, Workflow

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Method LifeCycle Management from Chromicent GmbH speeds up drug development considerably

Contribution of the Berlin-based company to coping with the "Corona crisis"

Events such as the coronavirus pandemic make us aware that access to innovative, affordable and safe medicines is one of the challenges of our time for the rapidly growing world population.

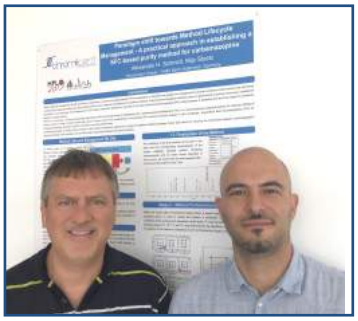
From its location in Berlin-Adlershof, Chromicent GmbH supports the pharmaceutical industry in the development of pharmaceuticals to combat and treat infections with the SARS CoV-2 coronavirus.

Dr. Alexander H. Schmidt, CEO:

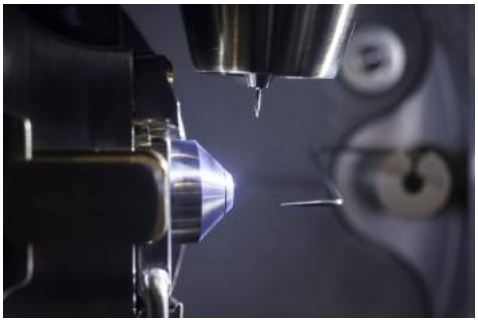
„With all our efforts in vaccine development, we have to keep in mind that a vaccine cannot help an immediately sick person – it must be administered preventively. That is why it is just as important to drive the development of new, innovative drugs to fight the virus. The method development platform of Chromicent GmbH accelerates exactly this development of pharmaceuticals considerably. We succeed in this by integrating quality-by-design principles while minimizing the risks."

In contrast to the empirically based methods used in traditional manufacturing and quality control, quality-by-design is a scientifically risk-based approach. An approach that is designed to integrate and ensure quality in a drug right from the start. On the one hand, this means significantly reducing development times and, on the other hand, preventing disruptions in the manufacture or quality of the pharmaceuticals.

As Mijo Stanic, second managing director and technical director, notes, that Chromicent uses the revolutionary method development and optimization software DryLab® from the Berlin Molnar Institute and on the leading chromatography data software (CDS) Empower 3 from Waters Corp.
By combining the two software programs, it is possible to drastically shorten the method development times, e.g. by optimizing the use of complex chromatographic systems and at the same time determining the most robust method conditions. By fully complying with the official requirements (EMA, FDA) for Method LifeCycle Management (MLCM), the quality of the results is significantly improved and ultimately patient safety is guaranteed.



The combination of innovative thinking, scientific expertise and many years of experience make the interdisciplinary team at **Chromicent GmbH the partner for all aspects of Method LifeCycle Management in drug development**.



Last but not least, a piece of news from the "entertainment" sector:

The ZDF has recognized the seminal atmosphere at Chromicent and will use the unique ambience of our laboratories as the location for a feature film in August. We are looking forward to this "somewhat different" experience and will of course keep you updated ...