- Nitrosamine -
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Dear customers and friends of Chromicent -

We hope you have had a good start to 2022.
At Chromicent, the beginning of the new year is marked by challenges and interesting assignments, which we implement professionally and closely to the wishes and needs of our customers.
Of course, this also includes a close exchange with you -

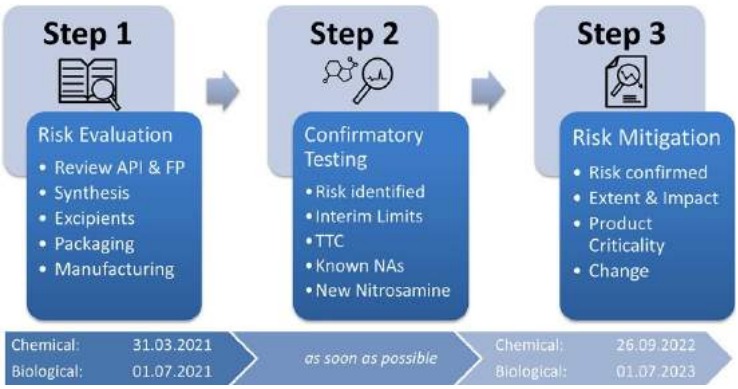
and it is a pleasure for us to keep you up to date on the current developments in our laboratory.

1 Nitrosamine - New publication

Nitrosamines continue to be an important topic in drug safety.
At an early stage, Chromicent published an SFC-based analysis method for sartans. In the meantime, we have further developed our analytical method and have already analysed more than 200 different APIs, finished medicinal products and excipients

– **thus nitrosamine analysis has become an integral part of our service portfolio.**

In our latest publication on the topic of nitrosamines, Chromicent focuses on the development of a method that can be used during the development of medicinal products **before authorisation** and **also in the risk assessment after authorisation**, in order to consistently avoid out-of-specification (OOS) results in the future.



The EMA has published a multi-stage approach with a strict timeframe (see figure below) for the implementation of an investigation procedure. This approach includes a risk assessment (step 1), additional confirmatory testing (step 2) and subsequent risk mitigation (step 3) when NAs are detected or highly probable.

The FDA has – most topically – given an update on the ongoing procedure last week.

FDA strongly recommends that **manufacturers and licence holders address "active substance-like nitrosamines".** The varenicline case has shown that not only small, aliphatic or aromatic amines (e.g. NDMA, NMBA, NMPhA) can be problematic, but also nitrosated active ingredients (in this case: N-nitrosovarenicline).

Since Chromicent has already developed and published a universal and selective SFC-MS/MS method for 16 aliphatic, cyclic and aromatic nitrosamines according to quality by design principles, the analysis could easily be extended to nitrosated pharmaceuticals, thus opening up a future perspective.

The full study can be found here:
Risk assessment for nitrosated pharmaceuticals: A future perspective in drug development

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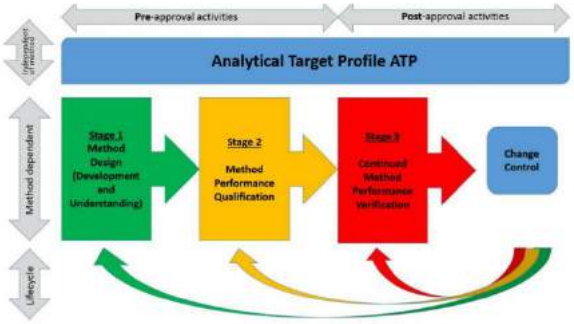
2 LIMS

We are currently implementing a laboratory and management system LIMS, which we have already engaged with intensively in advance and which will further optimise our already excellent level of digitalisation.
It enables us to take into account the increased requirements for data integrity.



3 MLCM

Method Lifecycle Management (MLCM) is one of the core competences of Chromicent.

Our constant expansion of the Quality by Design approach to method development, taking into account the entire lifecycle of an analytical method, will this year **focus on Stage 3** by **expanding stability and release tests and adapting them to customer needs.**

Parallel to our practical work, we will present new and expanded information material in a timely manner - to keep you up to date at all times on the possibilities and opportunities of this innovative and future-oriented approach.

4 Event

Of course, the topic of MLCM also includes a reference to our two-day seminar "**Lifecycle Management of Analytical Methods**". The organiser is Concept Heidelberg.

10-11 May 2022 - live online

We have compiled an exciting and informative agenda -
and we look forward to your participation.

Please note: the event is in German only.

Comprehensive information can be found
here