



Highly Potent Active Pharmaceutical Ingredients at CARBOGEN AMCIS

- **Interview with Dr. Anton Gayring**
Senior Head of Development at CARBOGEN AMCIS

CARBOGEN AMCIS has a strong expertise in the supply of Highly Potent Active Pharmaceutical Ingredients (HPAPI), many of them apply in the fields of oncology and ophthalmology. Besides process research and manufacturing services our HPAPI service portfolio is complemented by conjugation services for Antibody Drug Conjugates (ADC), fill-and-finish and lyophilization services for drug products. Dr. Anton Gayring – Senior Head of Development at CARBOGEN AMCIS – talks with us about this specialized capability and growing market.

- **Could you give a short explanation of the services that CARBOGEN AMCIS provides for highly potent (HiPo) substances.**

The services we provide are in general very similar to those we provide for normal active ingredients: We offer process and analytical development and production under cGMP – and of course regulatory affairs support if required. Our company's history reaches back more than 30 years, with over 15 years of experience in the field of highly potent substances.

- **Please give us a short overview of our sites, especially in terms of their HiPo capabilities.**

I would certainly start with our Vionnaz site where we purely focus on small scale category 4 HiPo niche products with reactor volume up to 30 L and supporting techniques such as HPLC (up to 10 cm), Biotage chromatography (20 kg) and lyophilisation (max 30 kg ice/batch).

Bubendorf can cover larger capacity requirements with up to 250 L reactor volume for category 4 and up to 1600 L reactor volume for category 3 respectively. Purifications can be supported with up to 10 cm HPLC and 40 kg Biotage. Our site in Neuland offers development activities up to category 3. In addition to this, our facility in Riom (France) is specialized in drug product services offering development and aseptic cGMP manufacturing for liquid and freeze-dried products including HiPo substances and ADC.

•• Have you noticed any changes in the field of HPAPI in the last years? Can you explain how this effected the business of CARBOGEN AMCIS?

The trends are pointing clearly in the direction of small scale highly potent molecules – APIs, payloads or linker-payload molecules – our categories 4 and 4+. Due to complex synthesis routes, instabilities and not developed routes, the focus is nowadays more in making the molecules rather than designing the most efficient manufacturing procedure. 10 years ago, the primary focus of our development labs was to feed our production capacity. Currently, a significant part of the HiPo development work is to feed small scale cGMP production up to a 1 kg scale. This comes along with requirements for chromatographic purifications. This trend triggered significant investments in the mentioned techniques at various scales and at all sites within the past years.

•• How do you think will the HiPo market develop in the future and which chances do you see for CARBOGEN AMCIS?

Of course it is difficult to look into the future. However, if the trends continue, we can establish ourselves as service provider for niche products, such as ADCs, Highly active APIs or high value molecules supporting downstream conjugations work. With the distinct service culture of our staff and the high quality and reliability of performed services, combined with compliance, we are looking positively into the future.

•• Can you explain the challenges that you are facing when dealing with HiPo compounds.

As mentioned above: we very often see poorly developed chemistry, long synthesis routes and very limited material availability of intermediates to do real process development. This is especially the case for the very active molecules of our categories 4 and 4+. Thus, it is very often the case, that the first multi-gram experiments have to be performed under cGMP to supply material for the next process steps.

•• What do you think are the key strengths of CGAM that made us successful in the field of HiPo? Why do you think CARBOGEN AMCIS is the right choice for a HiPo project?

Well, we have excellent people with the right skills and customer oriented mindsets. Their very strong experience is a real added value and we are very proud of this. Our state of the art equipment operates to the highest standards and helps us to ensure the high quality of our work. We are fully committed to managing the risks associated with handling and producing highly potent and toxic materials and are dedicated to maintain the safety of our employees and our environment. We fulfill the required regulatory and quality standards for each project phase. All this, along with our integrated service portfolio - including analytical support and technology transfer solutions - allows us to provide a tailor-made service for each project and each customer.

Did you know that CARBOGEN AMCIS...

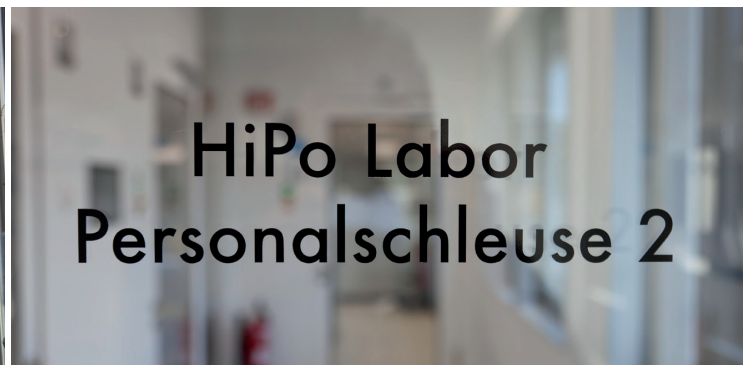
- ...has more than 15 years of experience in development & manufacturing of HiPo APIs?
- ...has the capability to handle up to Category 4+ compounds (<0.05 µg/m³)?
- ...has state-of-the-art containment technologies and a protection cascade system that ensure the workers' safety and product quality?
- ...has an in-house toxicologist for the categorization of all APIs and intermediates?
- ...HPAPI services reach from lab scale for process research and development purposes up to large-scale manufacturing in 1,600 L vessels?
- ...is active in the field of Bioconjugation and Antibody Drug Conjugates (ADC) since 2005?

•• Building 145, Bubendorf (HQ)

In September 2018 CARBOGEN AMCIS has expanded its operations at the headquarters in Bubendorf. The brand new additional facility building 145 has extended CARBOGEN AMCIS' laboratory capacity for highly potent development as well as analytical support.



HiPo Labor Personalschleuse 2



For more information about CARBOGEN AMCIS, visit www.carbogen-amcis.com

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