



Process Development in China at CARBOGEN AMCIS

- **Harry Wong, Ph.D.**

Senior Head of Development at CARBOGEN AMCIS Shanghai

Shanghai, the largest economic and trade center in China, hosts CARBOGEN AMCIS' fully self-supporting GMP compliant development and production site. The facility is located in the Shanghai Chemical Industry Park (SCIP) and is designed for large scale manufacturing of raw materials, intermediates and API. With an international team of highly qualified specialists, this facility can provide efficient and scalable solutions to customers globally.

Harry Wong, Senior Head of Development, speaks about Process Development at our site in Shanghai and shows a case study of a project for one of our customers.

- **What are the major tasks for the Shanghai Development team?**

„The Shanghai site has a focus on contract manufacturing service, therefore the major tasks for the development team are technology transfer and process development to support GMP production. In such sense, our job is to make the manufacturing process simpler, robust and to keep it reproducible to ensure a stable process and consistent good quality of the product.“

- **What are the greatest challenges for your team?**

„The group has positioned Shanghai as a site that specializes in large scale manufacturing of API and intermediates under GMP. Therefore, most of the projects we take are in transition from early phase to last phase. A common issue of these projects is that they often come with excessive in-process controls. It is completely reasonable that in early phase one may apply more in-process measures to gain better control and to have better understanding of process at scale. When a project evolves entering late phase and process performance is better understood, other KPIs such as process economy and throughput should be considered. However, it is always a challenge to convince the customer to reduce such control measures. The removal or streamline of in-process controls (IPC) at CARBOGEN AMCIS is performed by risk base approach - data of history batches including result of the IPC to be removed, analytical data and yield of corresponding batch will be collected; impact of product quality will be assessed; a proof of concept R&D run will be performed as demonstration; finally a change control will be initiated and presented to customer for approval.“

•• What are your responsibilities as Senior Head of Development at CARBOGEN AMCIS Shanghai?

As the head of the development department, my first priority is to build an effective and stable team with a group of trained chemists and project managers to support the operation and business expansion of the Shanghai site. To make our customer satisfied, we need to deliver our products and services in high quality and in time. An equally important responsibility for me is to ensure the project managers maintain focused on the team's goal and keep good communication with our customers to make the team working toward its objective.

•• Case Study

In a project entering phase 3 from phase 2 where there were many IPCs designed to monitor the waste streams, we successfully convinced the customer to remove 4 IPCs in a single step by the mentioned approach. The campaign gave product in similar quality and yield and batch time was much shortened.

| IPC | Purpose of IPC | Recent batch CA217-00116 | Recent batch CA218-00009 | Recent batch CA218-00016 | Risk Analysis |
|----------------|---|-----------------------------|-----------------------------|-----------------------------|--|
| IPC-12 (< Ref) | To control residual AP-I in aqueous (methanol/water) | in-spec | in-spec | in-sepc | <ul style="list-style-type: none"> •• IPC of recent batches all in-spec •• Product quality and yield of recent batches in-spec •• If IPC fails, minor loss of product in aqueous phase •• No quality impact to product |
| IPC-3 (< Ref) | Double check the residual content of AP-I in organic phase (cyclohexane) after phase separation | oos | in-sepc | oos | <ul style="list-style-type: none"> •• Product quality and yield of recent batches in-spec •• If IPC fails, minor loss of product in aqueous phase •• No quality impact to product |
| IPC-10 (< Ref) | Double check the residual content of AP-I in organic phase (cyclohexane) after phase separation | in-sepc | oos | in-sepc | <ul style="list-style-type: none"> •• Product quality and yield of recent batches in-spec •• If IPC fails, minor loss of product in aqueous phase •• No quality impact to product |
| IPC-5 (< Ref) | Double check the residual content of AP-I in aqueous phase after phase separation | oos | in-sepc | oos | <ul style="list-style-type: none"> •• Product quality and yield of recent batches in-spec •• If IPC fails, minor loss of product in aqueous phase •• No quality impact to product |



•• CARBOGEN AMCIS in Shanghai, China



Did you know that CARBOGEN AMCIS in Shanghai...

- ...is a 40'000qm site?
- ...has an international team (Chinese and expats) with more than 95 employees?
- ...can also support supply chain activities from GMP compliant purchasing to shipping customer ?



For more information about CARBOGEN AMCIS, visit www.carbogen-amcis.com
or www.carbogen-amcis.cn (Chinese)

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