

## Elizabeth Valero Speaks to Rhona McIntyre, Commercial & Marketing Director at CARBOGEN AMCIS



Rhona McIntyre.

### CAN YOU GIVE ME AN OVERVIEW OF CARBOGEN AMCIS AND WHAT YOURS AND YOUR TEAM'S ROLE IS WITHIN THAT?

CARBOGEN AMCIS is a contract research and manufacturing organisation based in Switzerland and the UK. We provide drug development and commercialisation services to the pharmaceutical industry, throughout drug development and lifecycle management. Our areas of focus are in process development, scale-up and small-scale commercial synthesis of APIs and intermediates, including highly potent APIs. In 2008 we were recognised for exemplary quality of manufacturing at our Bubendorf, Switzerland, site when the FDA conducted its latest inspections, and we have recently obtained the accreditation as foreign manufacturer for Japan. Our parent company, Dishman Pharmaceuticals & Chemicals, provides high quality, custom manufacturing and multi-tonne API production at locations in China and India. Being part of a truly global organisation with various manufacturing assets and locations allows us to offer customers a cost-effective commercial supply through economy of scale and location.

As Commercial Director, I oversee all sales, marketing and commercial functions for CARBOGEN AMCIS and I lead the team responsible for both new business sales and in-house commercial activities; in fact, all commercial functions from sale through to final invoice. The sales team is an experienced group of individuals, each based within their operating territory. We pride ourselves on the ability to understand customers' needs and to provide bespoke solutions from both a technical and regulatory perspective to support their drug development programmes.

### HOW LONG HAVE YOU BEEN WORKING FOR CARBOGEN AMCIS, WHAT HAVE BEEN YOUR ROLES AND WHERE DID YOU WORK PREVIOUSLY?

I have been working with CARBOGEN AMCIS for nine years, starting in a territory sales role in the UK and graduating to the role of Regional Manager for Europe. I have been in my current role for two years. Prior to joining CARBOGEN AMCIS, I worked for both clinical and preclinical companies in sales roles, starting out initially in an in-vitro cytogenetics lab. Overall, I have more than 20 years of experience in the pharmaceutical arena.

### WHAT UNIQUE CAPABILITIES IS CARBOGEN AMCIS ABLE TO OFFER ITS CUSTOMERS?

Our key differentiator is the high quality of the work delivered to our customers and the ability to tailor our services to their specific needs to support timely, cost-effective and safe drug

development and production. We have more than 30 years of expertise in API manufacture and our chemistry team has worked on a huge variety of reaction types. This depth and breadth of experience allows us to support customers with many synthetic and analytical challenges to produce cost-effective intermediates and APIs. Within CARBOGEN AMCIS we have centres of excellence in highly potent API production, chromatography services and analytics.

As part of the Dishman group, we are able to offer different manufacturing locations and fit-for-purpose non-GMP sites to FDA approved manufacturing facilities.

Last year, we handled over 400 projects per annum, more than 80% of which were return customers. We are proud of our customers' long-term success, which indeed reflects our unique offering in the pharmaceutical arena and our excellent customer service.

### HAS CARBOGEN AMCIS EXPERIENCED A SIGNIFICANT SLOWING DOWN IN BUSINESS DUE TO THE ECONOMIC DOWNTURN AND WHAT MEASURES HAS THE COMPANY PUT IN PLACE, OR RATHER WHAT CHANGES HAVE BEEN MADE, TO 'WEATHER THE STORM'?

The economic downturn has had plus and minus points for CARBOGEN AMCIS. On the minus side, there have been fewer early-phase projects available, meaning that there is more



API manufacturing facility (Bubendorf).



Headquarters (Bubendorf).

competition for projects and pressure on price. On the plus side, customers have been using their resources to progress their later-phase assets in order to increase their value. By virtue of our reputation for quality and experience in validation and commercialisation, CARBOGEN AMCIS has been able to secure and retain a number of exciting new projects.

### CARBOGEN AMCIS ANNOUNCED A RESTRUCTURING OF ITS SWISS FACILITIES LATE LAST YEAR — HOW HAS THIS PANNED OUT AND IN WHAT WAYS HAS IT BENEFITED CUSTOMERS?

The restructuring allowed CARBOGEN AMCIS to focus more resources on the late-phase projects, primarily at the Bubendorf site, and so better service the expanding market segment. In the early-phase area it has allowed us to reduce costs and to remain competitive within the changing market.

### CAN YOU TELL US ABOUT A RECENT CASE OF CARBOGEN AMCIS HAVING SOLVED A PARTICULAR DRUG DEVELOPMENT (OR OTHER) ISSUE FOR A CLIENT?

Unfortunately, we cannot disclose confidential information, however one recent example started with a lead optimisation project at mg-scale for a Californian start-up company. The timelines were very challenging and what started as a small development project rapidly developed into API supply for phase III material, process validation and commercialisation over a three-year period.

Along the way, the project was licensed to a major pharmaceutical company, a process supported with the CMC documentation of CARBOGEN AMCIS. Ultimately, this will lead to commercial launch in 2011 and continued material supply from CARBOGEN AMCIS.

Not only was the chemistry a challenge, but working with both companies to support their business requirements, as well as the specific demands of the project, required a successful team approach from all three of the parties involved.

### BACK IN JANUARY, CARBOGEN AMCIS ANNOUNCED THE OPENING OF ITS HIGH-POTENCY API MANUFACTURING FACILITY, SAID TO BE THE FIRST OF ITS KIND TO BE OPENED IN INDIA AND ONE OF ONLY A FEW SUCH FACILITIES WORLDWIDE. TO WHAT EXTENT HAS THIS EXPANDED/IMPROVED EXISTING CAPABILITIES (WHAT IS OFFERED THAT COULD NOT BE OFFERED BEFORE) AND WHAT PRODUCT GROUPS DOES IT PRIMARILY SUPPORT?

The containment principles and infrastructure of the new facility are based on the concepts developed during the construction of the Swiss high containment facility. The new facility allows us to offer an increase in scale up to 200 kg/batch at a similar level of OEL (Occupational Exposure Limit). We can now offer our customers competitive production of API to support lifecycle management for their high potency substances. This is in line with the market trend towards higher API volumes due to oral formulations in areas such as Tyrosine Kinase Inhibitors. An added service to support this is the implementation of a number of different milling options.



Small-scale, high potency production facility (Bubendorf).



API Custom Synthesis — PR&D Lab.

### WHAT NOW FOR CARBOGEN AMCIS? ARE THERE PLANS FOR FURTHER EXPANSION IN THE PIPELINE?

The Dishman Group has seen some exciting new developments in the past year, with the opening of the new containment facility, a new manufacturing site in Shanghai and a number of plant refurbishments in both India and Switzerland. We are therefore entering a period of consolidation. That said, we will continue to evaluate our technology portfolio to ensure that we can support the majority of new customer projects.

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