SO WHAT'S NEW?

THOMAS EISELE,
VICE PRESIDENT
CORPORATE R&D,
HOVIONE

+351 21 982 9405
teisele@hovione.com
www.hovione.com

CPhI worldwide
where intelligence gathers

"If you remember, at last year's CPhI we had just announced the opening of our R&D laboratory in Shanghai, which partners our China site. Since then, we have employed a team of 10 exceptionally talented individuals, all PhD and Master graduates in various disciplines. As well as ensuring the continual improvement of existing processes, these highly skilled employees are developing innovative processes for new generic compounds.

"We have also advanced in our ability to manufacture potent compounds. Hovione has upgraded its FDA inspected facility — an OSHA (Occupational Health and Safety Administration) VPP (Voluntary Protection Programs) 'Star' facility — in New Jersey to safely handle category 3a products (OEL of 1–10 µg/m^3) in all production areas by implementing a combination of engineering controls, which incorporate flexible and disposable containment systems. This site caters for pilot-scale manufacture of early stage clinical trial materials and low-volume commercial APIs.

"The FDA is now really pushing the QbD (Quality by Design) approach and this is a key differentiator for us — making Hovione really stand out in the market. Applying this approach together with one of our key customers, Hovione successfully passed its first PAI (Pre-Approval-Inspection) in April this year for a drug developed under a QbD framework. In fact, we have a number of late stage development projects in the pipeline using a structured QbD methodology.

"Perhaps the most important development has been the introduction of EDaM, which stands for Excellent Development and Manufacturing. EDaM was an 'idea' we had at the beginning of 2010, which evolved into a comprehensive guideline, aligned with the FDA and EMA, that is now implemented throughout the company, streamlining all operations worldwide.

"EDaM makes the most of Hovione's unique skills and knowledge by integrating development and manufacturing methodologies in a structured way across all areas within the company. This guideline links process development and manufacturing best practices and provides team members with guidance on what needs to be done at any stage of the development/manufacturing process, guaranteeing the right tools are always used in order to deliver the most value to our customers.

"EDaM brings together a diversity of scientific and operational disciplines that, working together with clear and simple goals and using the right set of tools, make Hovione the right partner to work with on developing and manufacturing new drugs. The training materials and templates available are two key elements to standardise its usage as they guarantee the right tools are used at the right time in each phase of the process.

"I gave a presentation on EDaM only last week and considerable interest was shown by attendees from several big pharma companies. Some specific comments clearly showed that many of them are heading in the same direction. This has definitely been a game changer for Hovione and speaking as one of its creators, I am extremely proud of what it has and will help us to achieve."