



In Small **Doses**

Flexibility for Clinical Trial and Pilot Drug Production Lines

Despite the current economic crisis, the drug development pipeline is still quite robust. There are 9,605 drugs being developed in 2009 according to the Pharma R&D Annual Review¹ published in May 2009. This is a plus of 2,400 compared to 2005 and almost twice as much as in 2000. Clinical trials are a critical component of the drug development process, determining which drugs will be taken to market and generate revenue to compensate for the costly R&D cycle.

Due to smaller production volumes, lines used to produce drugs for clinical trial operations have always had distinct needs in terms of processing equipment.

Additionally, a number of industry trends are changing the drug development landscape, and these changes are having important effects on clinical trial and pilot drug production.

New Players, New Drugs, New Demands

Drug R&D activities have traditionally been dominated by large multinational pharmaceutical companies - Big Pharma. Now the rising number of mid-size biotech and biopharmaceutical companies moving projects into clinical trials is affecting equipment demands.

While established players typically have existing clinical trial lines up and running,

this is not the case for new entrants, who, as an alternative to building their own lines, often outsource operations to clinical research organisations (CROs). This is just one reason why the global CRO market is expected to grow 14 % per year during the next three years, making contract research a 35 billion USD industry by 2013, according to a recent report from Business Insights². This growth has driven the need for new and improved filling and packaging machinery with increased flexibility.

Another change in drug development is the growth in production of injectable drugs, a market which is forecast to



reach 12.6 billion USD by 2010³, with growth in the biogenetic, oncology and vaccine segments expected to be especially strong. Biopharmaceuticals in particular are experiencing continuous growth, with a steady stream of products in the pipeline as well as several recent commercialisation successes. With regard to cancer treatment, 28 oncology drugs were approved in the EMEA (Europe, Middle East and Africa) region from 2005 to 2008 compared to 20 drugs between 1995 and 1999⁴. More focus is being paid to vaccines as well to address challenges in the area of infectious disease.⁵ Lastly, another trend greatly affecting the face of clinical trials is the move away from blockbuster drugs towards personalized medicine, or pharmacogenomics.

These trends are combining to change equipment needs for clinical trial production lines, as processing these types of drugs requires different sterile filling and finishing equipment than traditional

More Flexibility

One of the most prevalent demands in response to the abovementioned trends is the need for highly flexible machinery. CROs need equipment that can handle production of a variety of drugs to support multiple clinical trial operations, while personalized medicine and biotech drugs call for lower volume production runs.

With smaller batch sizes of 10,000 to 20,000 vials, manufacturers can no longer dedicate an entire filling line to one batch. Filling systems need to be used for multiple batches to maximize asset utilisation. Now, manufacturers and CROs need machinery that is able to fill multiple products with short startup times to increase efficiency. Flexible processing equipment also allows manufacturers to easily accommodate the handling of various components, including different sizes of stoppers, caps and vials, as well as to easily changeover between batches. Additionally, manufactur-

ers are also requiring modular machinery, allowing them to easily integrate new equipment into existing lines.

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¹ http://www.pharmaprojects.com/therapy_analysis/annual-review-2009.htm

² www.globalbusinessinsights.com/content/rbcr0015t.pdf

³ <http://www.in-pharmatechnologist.com/Materials-Formulation/Implantable-injectable-drug-delivery-market-set-to-hit-12.6bn-by-2010>

⁴ Development of Oncology Products. <http://appliedclinicaltrialsonline.findpharma.com/appliedclinicaltrials/article/articleDetail.jsp?id=605964>

⁵ <http://www.fiercevaccines.com/story/vaccine-market-trends-2009-predictions/2009-01-29#ixzz0Qicz0GTK>