A New Frontier: Biologics ELN

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The rapid increase of investment in biotherapeutics is changing the profile of the biopharmaceutical industry and, along with it, data management in the laboratory. With attention on longer patent life, high barriers to generic equivalents and personalized medicine, an increasing portion of R&D spending is being allocated to large molecule therapies, such as monoclonal antibodies.

This comes at the expense of investment on chemically synthesized small molecules. From 2005 to 2008, there were 73 new molecular entities approved by the FDA versus only 10 biologics. From 2009 to 2012, however, 24 biologics were approved versus 71 NMEs. According to Michael Elliott, founder, CEO and chief analyst at Atrium Research & Consulting, this growth will continue for the foreseeable future, as will investments in combination biopharmaceuticals, such as antibody drug conjugates that link biologics to small molecules.

The rapid pace at which biologics has grown has left most companies in informatics catch-up. Biologics is a far greater data management challenge than that for small molecules, and is a relatively new, emerging area for tools like electronic laboratory notebook software.

While a chemically synthesized compound’s process is fairly linear: from synthesis it flows quickly into tests for in vitro pharmacology, pharmacokinetics, etcetera. In contrast — for a series of assay and study results on a single molecular entity — just the process of creating a monoclonal antibody generates a multi-dimensional set of data requiring analysis.

Mike explains that there is no single way to attack the problem. It really comes down to: If a company wants a system to help support a change in process, then a

more complex tool needs to be carefully considered. This will take time and significant energy, but the rewards can be substantial in not only efficiency, but new insights into monoclonal antibody development process.

Although the “easy way” — what Mike calls the “paper-on-glass” electronic laboratory notebook, or ELN — is fine for those wanting to implement something that will improve knowledge capture and reuse, it doesn’t change processes.

With that being said, even for the “process enabling” ELN, best practices demonstrate the need to start simple and build over time, as change management is the biggest single challenge. People need to learn the tool to understand how it can be used to modify their workflows.

Read the complete article, “The New Frontier of Biologics ELN [1],” and more informatics coverage at our Web site www.scientificcomputing.com.

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