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SPECIAL FOCUS REPORT

PDMA 2010: The Power of Sharing

The PDMA Alliance is celebrating its 20th anniversary at this year's annual meeting, to be held in San Diego on Oct. 3-6. Here's what attendees can expect to learn and experience at the meeting.

LATEST NEWS

Thomson Reuters partners with specialist firm to provide API manufacturing-costs estimating

Date: 2010-09-23

Service will enable first-pass or competitive-intelligence estimating of production costs for active pharmaceutical ingredients based on patent literature

By combining the Newport suite of information services from Thomson Reuters (Philadelphia) with engineering and cost-estimating resources from Rondaxe Enterprises (Syracuse, NY), industry execs will be able to get accurate estimates of API manufacturing costs for generics (or even branded products where the information is available). That information, in turn, could help decisionmaking on appropriate contract manufacturing organizations (CMOs), due diligence on facility acquisitions, or competitive analysis of multiple generic manufacturers, say the firms.

With suitable patent-disclosure information and Rondaxe's CoGS (cost of goods sold) software, manufacturing costs can be estimated within 5-10%, says Kenton Shultis, president of Rondaxe—even where alternative synthesis routes and starting materials can represent literally hundreds of potential processes or facility designs.

Patent literature (which is the basis for the Newport service) is notorious for being written as much to obfuscate manufacturing processes as to describe actual requirements. But, according to Shultis, with enough experience in process design, raw material markets and production-equipment and staff requirements, reliable cost estimates can usually be defined. "Given a particular molecule or biologic, many cost estimators can produce an accurate result 80% of the time; with our storehouse of process knowledge, we can tackle the other 20% where small oversights such as the toxicity of intermediates can result in dramatic cost differences."

Rondaxe (which will be the point of contact for accessing the service) has developed a cost-estimating software program which it has sold to a small number of manufacturers to do their own cost estimating. The firm also provides consulting services on drug master files, CMC (chemistry, manufacturing and controls) regulatory filings and strategic analysis.

"We are delighted to partner with Rondaxe to strengthen our services to the generic and API manufacturing



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market," says Claude Bassett, VP of specialty markets at Thomson Reuters. "The partnership enables us to meet a demand from our clients for greater insight into the costs associated with manufacturing an API, which are often the most significant factor in the cost of goods of the finished generic drug."



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