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PUBLISHER Lisa Banket
EDITOR Taren Grom
CREATIVE DIRECTOR Marah Walsh

MANAGING EDITOR
Denise Myshko

SENIOR EDITOR
Robin Robinson

FEATURES EDITOR
Kim Ribbink

CONTRIBUTING EDITOR
Carolyn Gretton

DESIGN ASSOCIATE
Ariel Medel

NATIONAL ACCOUNT MANAGERS
Trish Kane
Cathy Tracy

WEBCAST NETWORK PRODUCER
Daniel Limbach

CIRCULATION ASSISTANT
Kathy Deiuliis

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Letters...

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Nurturing the Life Cycle

THE CHALLENGES FACING THE INDUSTRY — declining R&D productivity, a changing healthcare landscape, and increasing competition from generics, among others — have been well-publicized. In the past, cost-cutting measures, outcomes, and trial management improvements were employed to address productivity. But according to Oracle, new approaches need to be considered to make a meaningful impact. One such holistic approach is to focus on product life-cycle management (PLM), which is a business transformation approach to manage products and related information across the enterprise. PLM provides many pharmaceutical organizations with the ability to get products to market quicker and ensure greater regulatory compliance and efficiencies while reducing development costs.

Oracle has identified seven enabling best practices to support this transformation: drug development portfolio management; structured electronic drug development records (eDDR); integrated clinical supply development and management; technology transfer and collaboration; integrated quality and risk management; comprehensive packaging and collateral management; and global product registration. Oracle analysts say as pharmaceutical companies seek to have a unified view of their entire product development life cycle they need to be able to view and trace every product detail throughout the entire process. By having a unified view of the product(s) across the organization, companies can finally realize the benefits of cross-functional collaboration where product knowledge is transparent, and, thus, facilitating product governance both internally and externally (i.e., compliance with regulatory agencies).

According to Rob Bazemore, president of Janssen Biotech, in the next five to 10 years, companies will need to consider several core PLM elements or strategies.

One of the areas that companies will need to think about is the data requirements that will be needed at the time of approval/launch of a product.

"Although regulatory authorities may require the same efficacy and safety data, customers and payers will demand outcomes data, comparative data, and other information to determine reimbursement and comparative pricing," Mr. Bazemore says.

He says also there will need to be an increasing investment in services to maintain and support the use of brands. More attention and resources are being dedicated to introducing solutions for patients, not just products.

Finally, Mr. Bazemore says as biologic markets have become more attractive and crowded, the cycle times over which a product enjoys exclusive or differentiated positioning is shortening.

Regards,

Taren Grom
Editor

tgrom@pharmavoice.com

Their Word...

DENISE MYSHKO
Managing Editor

Epigenetics is leading to a new understanding of biologics and to new targets for new drugs.

ROBIN ROBINSON
Senior Editor

New strategies started earlier can make PLM more effective, but don't confuse that with easier.

KIM RIBBINK
Features Editor

With its diverse population, developed infrastructures, and political stability, South Africa offers not only an excellent center for research and product development, but a gateway into the rest of Africa.

CAROLYN GRETTON
Contributing Editor

It's gratifying to see that pharma marketers are starting to embrace how much more educated and savvy consumers are, and that they are looking at this as a positive rather than as something to be suspicious or fearful of.

COMING *in November/ December*

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- R&D, Clinical Operations, Marketing, Sales, Outsourcing, Regulations, Emerging Markets, and more
- Showcase Feature — eSolutions