PharmaVOICE
THE FORUM FOR THE INDUSTRY EXECUTIVE
Volume 3 • Number 2

PUBLISHER Lisa Banket
EDITOR Taren Grom
CREATIVE DIRECTOR Marah Walsh

DIRECTOR OF SALES
Darlene Kwiatkowski

MANAGING EDITOR
Denise Myshko

CONTRIBUTING EDITORS
Elisabeth Pena
Kim Ribbink
Alex Robinson
Lynda Sears

PharmaVOICE is published 12 times per year by PharmaLinx LLC, P.O.Box 327, Titusville, NJ 08560.

Postmaster: Send address changes to PharmaVOICE, P.O. Box 327, Titusville, NJ 08560.

PharmaVOICECoverage and Distribution: Domestic subscriptions are available at $160 for one year (12 issues). Foreign subscriptions: 12 issues US$330. Contact PharmaVOICE at P.O. Box 327, Titusville, NJ 08560. Call us at 609.730.0196 or FAX your order to 609.730.0197.

Contributions: PharmaVOICE is not responsible for unsolicited contributions of any type. Unless otherwise agreed in writing, PharmaVOICE retains all rights on material published in PharmaVOICE for a period of six months after publication and reprint rights after that period expires. E-mail: tgrom@pharmavoice.com.

Change of address: Please allow six weeks for a change of address. Send your new address along with your subscription label to PharmaVOICE, P.O. Box 327, Titusville, NJ 08560. Call us at 609.730.0196 or FAX your change to 609.730.0197. E-mail: mwalsh@pharmavoice.com.

IMPORTANT NOTICE: The post office will not forward copies of this magazine. PharmaVOICE is not responsible for replacing undelivered copies due to lack of or late notification of address change.

Advertising in PharmaVOICE: To advertise in PharmaVOICEplease contact our Advertising Department at P.O.Box 327, Titusville, NJ 08560, or telephone us at 609.730.0196. E-mail: lbanket@pharmavoice.com.

Letters

Send your letters to feedback@pharmavoice.com. Please include your name, title, company, and business phone number. Letters chosen for publication may be edited for length and clarity. All submissions become the property of PharmaLinx LLC.

Clinical obstacles

Lessons can be learned from other industries that have explored how to best achieve change, NASA for example. Drug development is indeed like rocket science. It is complex, unpredictable, and requires relentless proactivity to ensure mission success.

With drugs costing an average of $800 million and taking 10 years to 15 years to develop, pharmaceutical and biotechnology executives have no choice but to improve R&D productivity and get new products to the market more quickly.

To do so, the clinical-trial process needs to be streamlined for improved efficiency. Hampering efforts, however, is the fundamental nature of research and development.

"Unpredictability is the one feature that is guaranteed to challenge — and derail — project performance in a clinical-development program," says Lawrence A. Meinert, M.D., MPH, senior VP of global clinical operations for Covance Inc. "Years of efforts have been expended to enhance clinical management throughout the drug-development industry. It is nearly universally understood that clinical trials consistently underperform within the areas of enrollment rates and staffing. The goal is clear, however: meet the numbers established in the protocol that can be easily tracked and measured by the standard arsenal of project-management tools. And yet again and again, project management fails to deliver on-time, on-target completion of these simple-to-articulate, but difficult-to-deliver, success critical goals."

Much of the responsibility of delivering on the critical goals of a project falls on the shoulders of project managers or team leaders. These professionals often are required to perform Herculean tasks — coordinate physician investigators, manage patient-recruitment efforts, adapt to new technologies, communicate with diverse teams across a project, gather and assimilate vast amounts of data, among other functions.

Project managers, according to industry experts, are the nuts and bolts that hold the project together. They must be strong leaders, able to motivate a team, keep projects on schedule, and deliver quality.

"Project managers need to be well-rounded, they need to have adequate knowledge of the drug-development process, and of the processes associated with individual clinical trials," says Karen Wolf, VP of strategic account management at AAI International. "They need to have enough knowledge to manage a multidisciplinary team of people. They don't have to be experts in any one discipline, but they do have to have enough knowledge to manage the team credibly."

For project managers to meet all the requirements necessary for successful project outcomes, industry leaders maintain that the process must change. Dr. Meinert suggests that lessons can be learned from other industries that have explored how to best achieve the necessary changes.

"Look at NASA for example," he says. "For years NASA operated its robotic missions under the same model as the drug-development industry: faster, better, cheaper. But such an approach leads to a profound risk of catastrophic failure, as we saw in the Mars Polar mission disasters. As a result, NASA developed an approach called 'continuous risk management.'"

Dr. Meinert says this methodology can be applied to scientific management.

"Drug development is indeed like rocket science," he says. "It is complex, unpredictable, and requires relentless proactivity to ensure mission success."

Taren Grom
Editor