

THE QUALITY ASSURANCE



PODCAST

Smart, Simple, and Sustainable Solutions.

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PRN Pharmaceutical
Research Network, LLC



EPISODE 2

TRAINING THAT TRANSLATES: PRACTICAL PREPARATION FOR GXP PERFORMANCE



CHRIS MILAWSKI

JEANETTE STEWART

ASHLEY HEHR

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IN THIS EPISODE

- Continuing Education vs. Baseline Training
- Topics for short but smart trainings
- SOPs, Trainings, and Collective Performance
- Fun and Interactive Trainings
- Proactive Protocol Training
- Regulatory Impact of Training
- How PRN can help with your training needs.



BEYOND THE BASELINE TRAINING

The Problem: Initial baseline training, such as annual or biannual Good Clinical Practice (GCP) or 21 CFR Part 11 training, is necessary but insufficient on its own because people easily forget what they learned.



The Solution:

Organizations must invest in ***continuous education*** to ensure employees maintain their knowledge, stay up to date, and apply it to their specific roles.

Micro-Learning:

using short, smart 15- to 30-minute sessions rather than long, drawn-out training sessions.

TOPICS FOR SHORT & SMART SESSIONS

- ✓ Monitoring
- ✓ Medical oversight
- ✓ Safety reporting
- ✓ ALCOA principles
- ✓ Examples of lacking or missing elements in source documentation procedures
- ✓ Common observations during monitoring visits
- ✓ Regulations and guidances
- ✓ Processes and procedures



Training is so important for everyone.

[They need] to understand that there are so many things going on, and if you're not honing your skills and you're not fully up to date on rules and regulations and things...

I don't want to say doomed to fail, but *you're making your life a lot harder.*

CHRIS MILAWSKI

Host, The QA Podcast
Senior Clinical Research Associate, PRN

SOPS, TRAININGS, & COLLECTIVE PERFORMANCE

Moving Past Read-Receipts: When standard operating procedures (SOPs) are updated, companies usually just ask employees to read and sign them.

Understanding Impact: Ashley recommends interactive SOP reviews in which employees map out how their specific roles affect processes upstream and downstream.

Building Ownership: By understanding how a project manager's work might affect data management, employees gain a broader understanding of the clinical umbrella and take more ownership of their tasks.



A lot of people, once they come together,
they realize they're not in a silo,
that what they're doing could impact
upstream or downstream,
**they start taking a little bit more
ownership.**

ASHLEY HEHR

Quality Assurance Expert



MAKING TRAININGS FUN!



- ✓ Gamify the workshop (e.g., case study with exclusion/inclusion criteria)
- ✓ Provide prizes (e.g. \$25 Amazon Gift Card)
- ✓ Use leaderboards
- ✓ Offer snacks/foods!

PROACTIVE PROTOCOL TRAINING

- **The Pitfalls:** Often, protocols are briefly reviewed at a kickoff meeting and then forgotten.
- **Vetting Potential Issues:** Teams should hold specific training sessions to discuss potential pitfalls, vague medical history requirements, inclusion/exclusion, and other possible errors before going out into the field.
- **Mitigating Mistakes:** While protocol deviations are inevitable, thoroughly training staff on the protocol's nuances minimizes the risk of errors and uphold quality across all stages of the clinical research.

THE REGULATORY IMPACT OF TRAINING



Ashley, what are the first three things the FDA regulator will look for when they walk into your site?

Employee training. They're also going to interview people and understand how much they really know. So this is where these small lunch-and-learns, these 15-minute segments, really come into play. Because that's going to allow somebody to shine. And it's going to be very imminent **when they start talking that they understand their role** and the other roles around them.



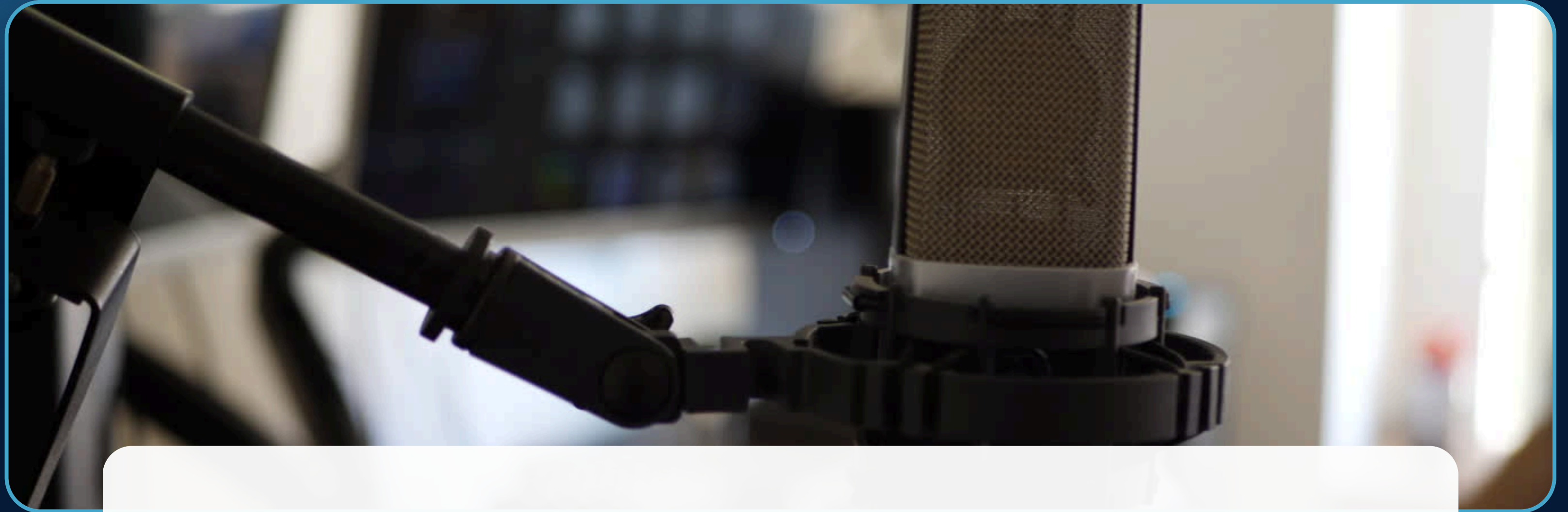
And could you imagine how shocked an inspector would be if the people being interviewed actually got excited about training? That will surely be surprising!

LET'S BUILD YOUR TRAINING CULTURE TOGETHER!



PRN Pharmaceutical
Research Network, LLC

CONTACT US



 **Website**

www.prnob.com

 **Phone**

+1 843-606-0776

 **Email Address**

info@prnorb.com

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