

Driving to Phase I

(and beyond!)

TOPICS

TRAINING ARRANGEMENTS

Clinical Trial Materials Training

How to Get your Drug From Research into Man

After participating in this training you will be able to:

- Adhere to the Rules of the Road [Current Good Manufacturing Practices (cGMP)]
- Navigate Obstacles & Avoid Detours
- Calculate a Realistic Delivery Date for your Clinical Trial Materials

Plan for success!

Who should attend?

- Researchers
- Clinical Development
- Clinical Project Managers
- Venture Capitalists
- Design Engineers (Medical Device)

Safety First - connection between drug (API or early formulations) and safety/toxicology

Rules of the road – cGMP regulations governing the manufacturing, testing, packaging, labeling and use of clinical trial materials

Who's driving? - Roles and responsibilities of 'clinical' versus 'clinical materials'

What's the route? – Milestones and destinations

S-curve: Sterile product challenges – highlights of environmental controls, microbiological controls and testing required to ensure product safety

Miles to empty - Stability data and use-by-date justification

Are we there yet? – Functional roles and activities associated with manufacturing, packaging, & labeling, releasing and distributing clinical trial materials

Contact Global Clinical Connections to schedule this 1-day training at your facility. Materials and content may be customized to reflect local terminology or to satisfy your particular needs.

Phone: (269) 488-3277 or
E-mail: lacdubray@globalclinicalconnections.com

FEES:

Registration: **\$200/participant (minimum 5)**, plus Travel expenses for trainers. Fees for material/program customization are negotiable.

About the Trainers:

Trainers will be members of the Global Clinical Connections team. Each brings an extensive, and unique blend of experiences in the clinical trial materials arena, including drug product forecasting, formulation development, device qualification, manufacturing, vendor management, packaging & labeling, and distribution of clinical trial materials.





**Regulated
Environment!**

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Training at your facility provides a cost effective way to include your entire team. Make arrangements by contacting:

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Global
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Kalamazoo, MI 49009
www.globalclinicalconnections.com
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