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# Global Compliance with EU PV System Requirements

Presented by  
Lynn D. Van Dermark, MedTrials, Inc.  
and  
Regina Freunscht, Accovion GmbH

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# Presentation Overview

- PV Background and Overview
- Reference Standards
- Volume 9A and EU PV Requirements
- Global Compliance...
  - PV System Requirements
  - Tools and Procedures
  - Training and Education
  - Quality Control and Quality Assurance
- Conclusion and Summary Remarks

## Learning Objectives

1. Describe the key elements driving an effective PV system.
  2. Identify strengths and challenges in a PV system.
  3. Identify departments and third parties to be included in an effective PV communication system.
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# Conclusion

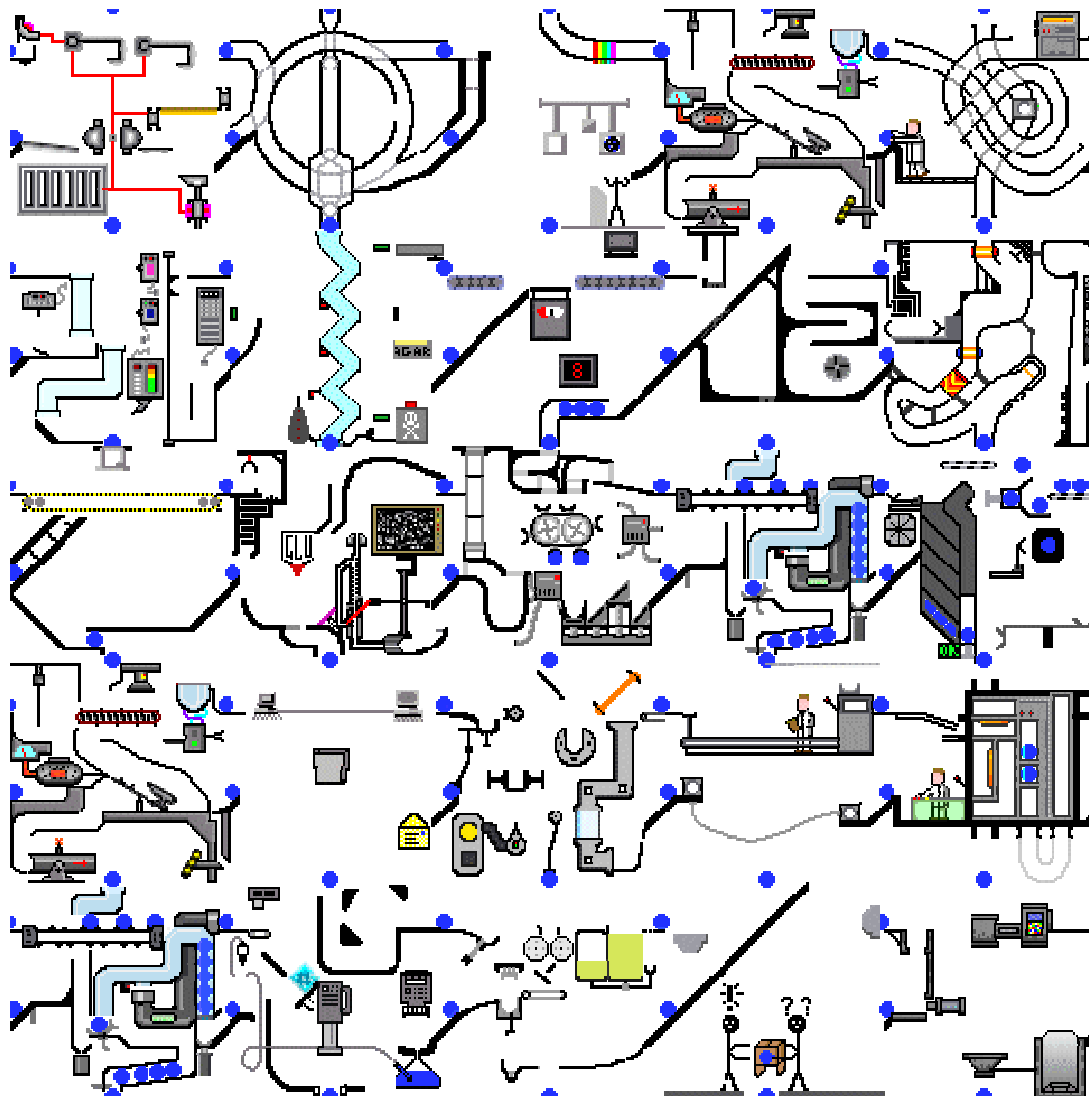
- Statutes and regulations are present to help insure the integrity of reporting and for the protection of the consumer
- Failure to comply with regulations can result in serious consequences
- Willful disregard for regulations is considered misconduct
  - Misconduct is the deliberate falsification of data, proposing designing, performing, recording, supervising or reviewing processes

# Conclusion

- Good faith compliance required by all
  - Commitment to honesty, integrity and openness is essential
  - Compliance with company standards and procedures, applicable national and local laws as they relate to pharmacovigilance is mandatory
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# Questions



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# Thank you !

## Lynn D. Van Dermark

CEO  
MedTrials, Inc.  
2777 N. Stemmons Freeway, Suite 900  
Dallas, Texas 75207  
Phone: 214.630.0288 x227  
Fax: 214.630.0289  
[lvandermark@medtrials.com](mailto:lvandermark@medtrials.com)  
[www.medtrials.com](http://www.medtrials.com)

## Regina Freunschdt

Director Marketing and Communication  
Accovion GmbH  
Helfmann-Park 10  
65760 Eschborn, Germany  
Phone: +49 6196 7709 442  
Fax: +49 69 305 877 00  
[regina.freunschdt@accovion.com](mailto:regina.freunschdt@accovion.com)  
[www.accovion.com](http://www.accovion.com)