

**FDA, PDA, GAMP Information
Exchange, May 23, 2001**

**Up-date on PDA Task Group and
GAMP Activities**

Agenda

- Opening (15 min)
- Charter and accomplishments (15 min)
- Work product updates (20 min)
- GERM Conference (20 min)
- Affiliations with other groups (20 min)
- Q&A (20 min)
- Closing and Next Steps (10 min)

Opening Remarks and Introductions

PDA TG Charter

- **Primary**
 - Endorse electronic record keeping practices which make sense for FDA regulated companies and which are consistent with 21CFR Part 11
- **Secondary**
 - Propose models to facilitate conformance with industry ‘good practices’ and help companies with their compliance activities resulting in a win-win for all stakeholders

Deliverables

- Describe Current Good Electronic Records Management (GERM) Practices
 - Surveys (Industry, Agency, Suppliers)
 - Research (Existing Practices, Legal)
 - Coordinated Efforts
 - Glossary of Terms
- Legacy System Model
- New System Model
- Supporting Infrastructure

Accomplishments

- Survey of Needs
 - Supplier and Sponsor - completed
 - Agency – tabled
- On-going monitoring of Main Stream events
- Established Cooperative Efforts
- Conferences
- Work products in development

Sponsor Survey Highlights

- 19 surveys returned
- Obstacles and concerns for legacy systems
 - strategic plan and dedicated resources
 - audit trails, record retention, signature linking
 - encryption tools
- Obstacles and concerns for new systems
 - compliant suppliers
 - audit trails, detection of altered records signature linking

Supplier Survey Highlights

- 13 surveys returned
- Most believe they understand the regulation
- All were comfortable with the terms and definitions
- Nearly all indicated that the capability of A & A exists with their products
- Device checks was somewhat puzzling.
- Electronic signing via PW and ID codes can be implemented

Conference

- FDA/PDA Public Conference Part 11 - June 200
 - CD ROM Available
- PDA/FDA September Conference
 - Panel Session on e-Rec and e-Sig
 - Highlights of Public Conference
 - Round Table Lunch

Status of Work Products

- GERM – Working Draft “Straw Man to Stone Man”
 - **4 Sections** devoted to concepts and facts relating to e-records from a life cycle perspective and legal implications
 - **6 Sections** that relate to current good practice in using and applying technology to the management of e-records
 - **Glossary (in development)**
- Start comment period (Testing) - End May
 - Stakeholder (supplier, regulated companies, service providers, and FDA)

Status of Work Products

- Legacy Model – In development
- Two concepts for model
 - Phased approach - focus is technology
 - Maturity approach - focus is informational object

Status of Work Products

- New Systems Model - Recently launched
- Focus is industrial strength systems design
 - Requirements engineering heftier concentration on informational objects
 - Engineering survivable systems; concentration on COTS

Status of Work Products

- Supporting Infrastructure - Education Framework
 - Evaluation of current TRI Courses
 - Align with TG Work Products
 - INFOSEC Course
 - Computer Validation Key Practices
- Metrics program

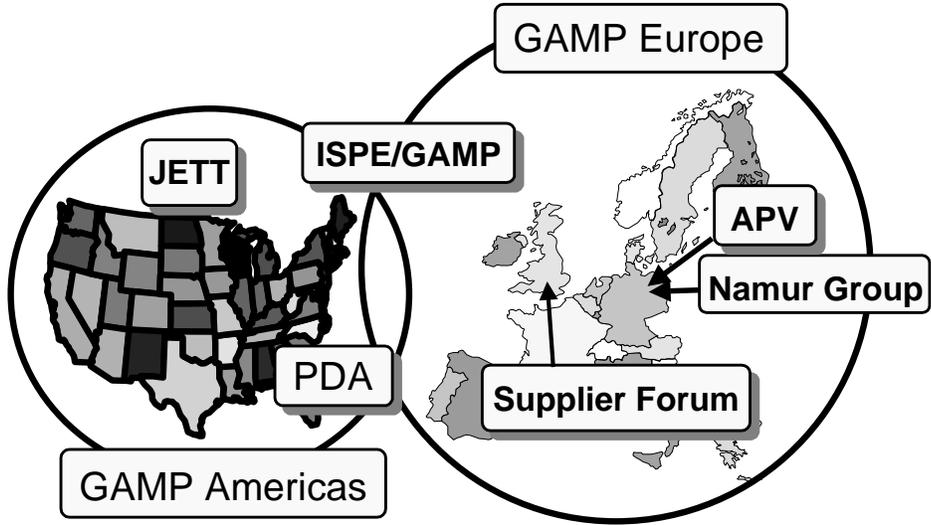
ISPE/GAMP

G. Wingate

Chairman, GAMP Industry Board

Work product content integration

GAMP Alliance



Part 11 Guidance

- 1. Introduction**
- 2. Objectives**
- 3. Scope**
- 4. Management Approach to Achieving Compliance**
 - 4.1 Introduction to the Approach**
 - 4.2 Achieving Compliance - The First Steps**
 - 4.3 Achieving Compliance for New Systems -
Guidance for Users and Suppliers**
 - 4.4 Achieving Compliance for Existing Systems**
- 5. Conclusions**
- 6. Appendices**

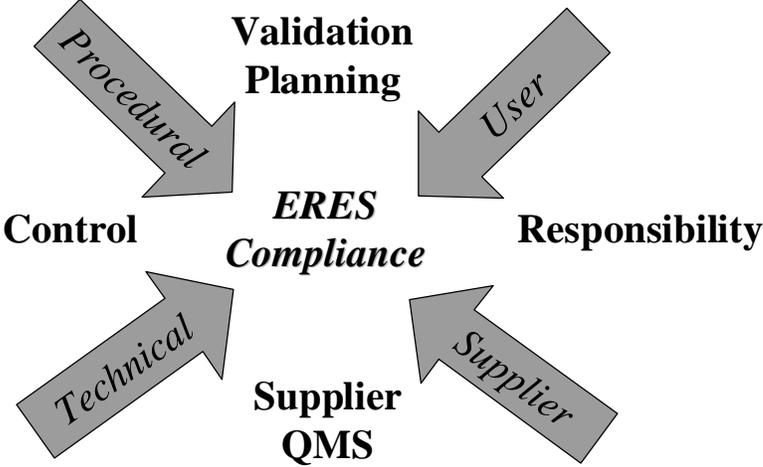
Appendices

- 6.1 Appendix 1 - Annotated 21 CFR Part 11 Rule**
- 6.2 Appendix 2 - Types of Controls Systems**
- 6.3 Appendix 3 - System Assessment Checklist**
- 6.4 Appendix 4 - Key Area for Guidance**
- 6.5 Appendix 5 - Examples of Applying 21 CFR Part 11**
- 6.6 Appendix 6 - FDA Compliance Policy Guide;
Enforcement Policy**
- 6.7 Appendix 7 - Electronic Documents and their
Management Lifecycle**
- 6.8 Appendix 8 - Examples from Warning letters**
- 6.9 Appendix 9 - Glossary**
- 6.10 Appendix 10 - References**

EU Mapping

- EU GMPs Annex 11 - Computerised Systems (for electronic records)
- EU Directive 1999/93/EC - Electronic Signatures
- ISO 17799 - Information Security Management (good practice for electronic working environments)

Supplier Role



Next Steps

- GAMP4 being prepared for publication in Q4, 2001
- GAMP4 extended to give a more comprehensive coverage for projects, handover, operation and maintenance, and decommissioning
- GAMP Part 11 Guide will be a good practice document to accompany the main body of GAMP4

Overview of GAMP Guidance (GAMP4)



GERM Conference

J. McKenney

GERM Conference

(Good Electronic Records Management)

- April 2-6, 2001
- Tampa, Florida
- Primary Drivers:
 - Promote good e-recordkeeping practices
 - Promote the PDA TG GERM work products
 - Address “gaps” identified with joint FDA/PDA Part 11 conference last June, 2000

GERM Conference

- What were the June conference gaps?
 - Too many vendor sales pitches
 - Too few pharma company presentations
 - Too short (20 mins. not enough for good topics)
 - Too little FDA participation
 - Unmet (and unrealistic) audience expectations

GERM Conference

- How did we address the gaps?
 - Call for Papers: not too successful, as expected
 - Personal Invitations: highly successful, with strong industry participation¹
 - Presentations extended to 45 minutes
 - Invited FDA to present closing plenary session
 - Managed expectations via detailed brochure

¹Pharma companies slated to make presentations include:

- Abbott Laboratories
- Amgen
- Bristol-Myers Squibb
- Centocor
- DuPont Pharmaceuticals
- GlaxoSmithKline
- Janssen Research Foundation (J&J)
- Pfizer
- Pharmacia

GERM Conference

- What made this conference unique?
 - Addressed all phases of the e-record lifecycle
 - Offered multiple concurrent tracks
 - Included substantial pharma industry participation
 - Involved “heavy hitters” outside the industry¹
 - Offered pre- and post-educational sessions²

¹Special guest speakers include:

- Charles Dollar – former NARA e-records authority
- Randy Kahn – attorney with background in complex document-based litigation
- Jeff Rothenberg – RAND Corp. Senior Computer Scientist; author of *Scientific American* article on long term e-records retention
- Kathie Dudley – attorney and former judge with substantial records management experience

²Pre- and post-educational sessions offered:

- Computer Products Supplier Auditing Process Model
- Introduction to 21 CFR Part 11 (the basics)
- Computer Validation Key Practices
- Training

GERM Conference

- GERM Conference Goals
 - Promote GERM practices (and PDA efforts)
 - Increase understanding of Part 11 concepts
 - Provide practical case studies and solutions
 - Promote networking and information exchange
 - Support FDA's mission to educate industry on Part 11

GERM Conference

- Post-Conference Summary
 - Feedback was very positive
 - Many participants said it was the best Part 11 conference they had attended
 - Industry “outsiders” expanded our thoughts and discussion well beyond the normal Part 11 paradigm (i.e., they gave us many reasons for managing e-records beyond 483 avoidance)

Initiative Affiliates

- ISPE/GAMP
- Other Organizations
- Related, SEI

PDA Working Relationships, ISPE and CENSA - R. Madsen

- PDA and ISPE have agreed to co-publish the combined Part 11/GAMP report. A joint task force has been established to coordinate the effort.
- PDA will delay formal working relationship with CENSA pending additional study and resources.

Initial PDA considerations regarding CENSA were that the missions and purposes of the two organizations are somewhat different. Currently, PDA hasn't the resources to support a relationship. We may want to open the relationship in the future.

Other Organizations

- AdvaMED (formerly HIMA) - 1 CT
- MDMA - 2 ET
- CENSA - 1 ET
- PhRMA Coalition - 4 ET

Related Affiliate

- SEI - Collaborative work agreement with PDA; COTS Initiative; April 10-12, 2001
 - Case Study and SEI TR on PDA and ARC TR-32
 - COTS Training evaluation and deployment via PDA-TRI
- Supportive of Part 11 Pre-requisite for Supplier Evaluation of COTS products and Computer Validation; (FDA Guidance)

Q&A

Closing and What's Next