



Case Study: Training Methods and Tools to Achieve HIPAA Privacy and Security Compliance

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by

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Case Study: Training Methods and Tools to Achieve HIPAA Privacy and Security Compliance

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Agenda

- Overview of HIPAA Training Requirements
- Guiding thoughts on e-learning and assessment
- LearnWright's Models of Instruction and Assessment in a Pharmaceutical Manufacturing Context
 - Knowledge and cognitive (decision-making) skills
 - Motor skills
- Applying the LearnWright Model to HIPAA Training



Overview

- Outline of HIPAA Privacy and Security Training Requirements.
- Case Study focused on the pharmaceutical industry.
- Use a model with the following focal points: analyze, design, develop, implement, evaluate, revise.
- Life-cycle approach to creating training applications.
- Emphasis on creating unique Models of Instruction and Assessment.



HIPAA Privacy Training

- “A covered entity must train all members of its workforce on the policies and procedures with respect to protected health information [PHI] required by this subpart as necessary and appropriate for the members of the workforce to carry out their function within the covered entity.” (164.530(b))
- Implementation
 - Training methods and materials not specified.
 - Training must be provided to each member of the covered entity’s workforce no later than the compliance date for the covered entity:
 - April 14, 2003 for most covered entities.
 - April 14, 2004 for small health plans.
 - After compliance date, new workforce members must be provided training in reasonable time (e.g., during orientation).
 - Training must be provided to workforce members whose functions are affected by a material change in policies and procedures in a reasonable time after the change(s).
 - A covered entity must document in written or electronic form that the training has been provided, with documentation retained for six years.



HIPAA Privacy Training

- Business Associates
 - Covered entities have a responsibility for breaches of privacy by their business associates.
 - Covered entities are not required to monitor business associates' establishment of specific training requirements.
 - Solution may be to establish a training requirement in a business associate contract as a means to protect health information provided to a business associate.
 - Insurance liability issues to consider.
 - Potential civil and criminal penalties.
 - Adverse customer reaction.



HIPAA Security Training

- Proposed rules published in the Federal Register on August 12, 1998.
- Goal is “to protect the confidentiality, integrity, and availability of individual health information.”
- Four areas addressed.
 - Administrative Procedures to Guard Data Integrity, Confidentiality, and Availability.
 - Physical Safeguards to Guard Data Integrity, Confidentiality, and Availability.
 - Technical Security Services to Guard Data Integrity, Confidentiality, and Availability.
 - Technical Security Mechanisms to Guard Against Unauthorized Access to Data that are Transmitted Over a Communications Network.
- Training requirements fall under Administrative Procedures.



HIPAA Security Training

- Training
 - Provide security training for all staff and contractors having access to healthcare information regarding the vulnerabilities of the health information in an entity's possession and policies and procedures must be followed to ensure the protection of that information.
 - Provide awareness training for all employees, including management. Training, at a minimum, shall include:
 - Applicable laws and regulations concerning privacy and security of healthcare information and the associated penalties for violating these laws and regulations.



HIPAA Security Training

- Training
 - Provide awareness training for all employees, including management. Training, at a minimum, shall include:
 - Virus awareness, detection, updating virus software, and incident reporting and response.
 - All security policies and procedures and sanctions associated with violation.
 - Physical access controls, including opening, closing, after-hours, and emergency access.
 - Procedures for reporting security policy and procedure incidents, violations, and associated responses.



HIPAA Security Training

- Training

- Provide awareness training for all employees, including management. Training, at a minimum, shall include:
 - Usage of access controls in place, including, but not limited to, user ID, passwords, tokens, and biometrics, with a focus on rules for creating, using, changing, and keeping confidential.
 - Provide training as part of new employee orientation with annual retraining in a regular training schedule.
 - Implement measures for periodic security reminders, such as monthly or quarterly emails, intranet bulletins, or bulletin board postings.
 - Provide training on the importance of monitoring login success and failure rates and how to report discrepancies.



HIPAA Privacy and Security Training

- While privacy and security training methods are not defined, training content is complex, requiring proven learning methods.
- Solution:
 - Computer-based business model.
 - Takes advantage of the Internet.
 - Provides better value than alternative training methods and deployment strategies.
 - Has important characteristics:
 - Integrates innovative use of graphical, audio, and video/still picture media, validated instructional design techniques, comprehensive knowledge of federal regulatory rules, and a covered entity's policies and procedures.



HIPAA Privacy and Security Training

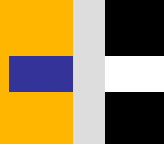
- Solution has Important characteristics
 - It categorizes regulatory rules and procedures according to job function and employee profile.
 - It permits employees to learn independently, to self-pace learning, and to focus on areas for which an employee needs additional learning time.
 - It audits employee compliance with training initiatives.
 - It provides employee performance measurement.
 - It provides centralized, maintainable, and secure documentation.
 - It provides a consistent, standardized delivery.
 - It minimizes travel costs to receive training out of the office.
 - It minimizes time away from work.
 - It is cost-effective when compared with costs of traditional classroom learning.
 - It is cost-effective and current when compared with costs of printed training documentation that may need frequent updates.



The Current State of e-Learning

“Nearly 90% of e-learning today is based upon a model of tutorial instruction more than 25 years old.”

Roger Schank
Designing World-Class e-Learning
New York, McGraw-Hill
2001

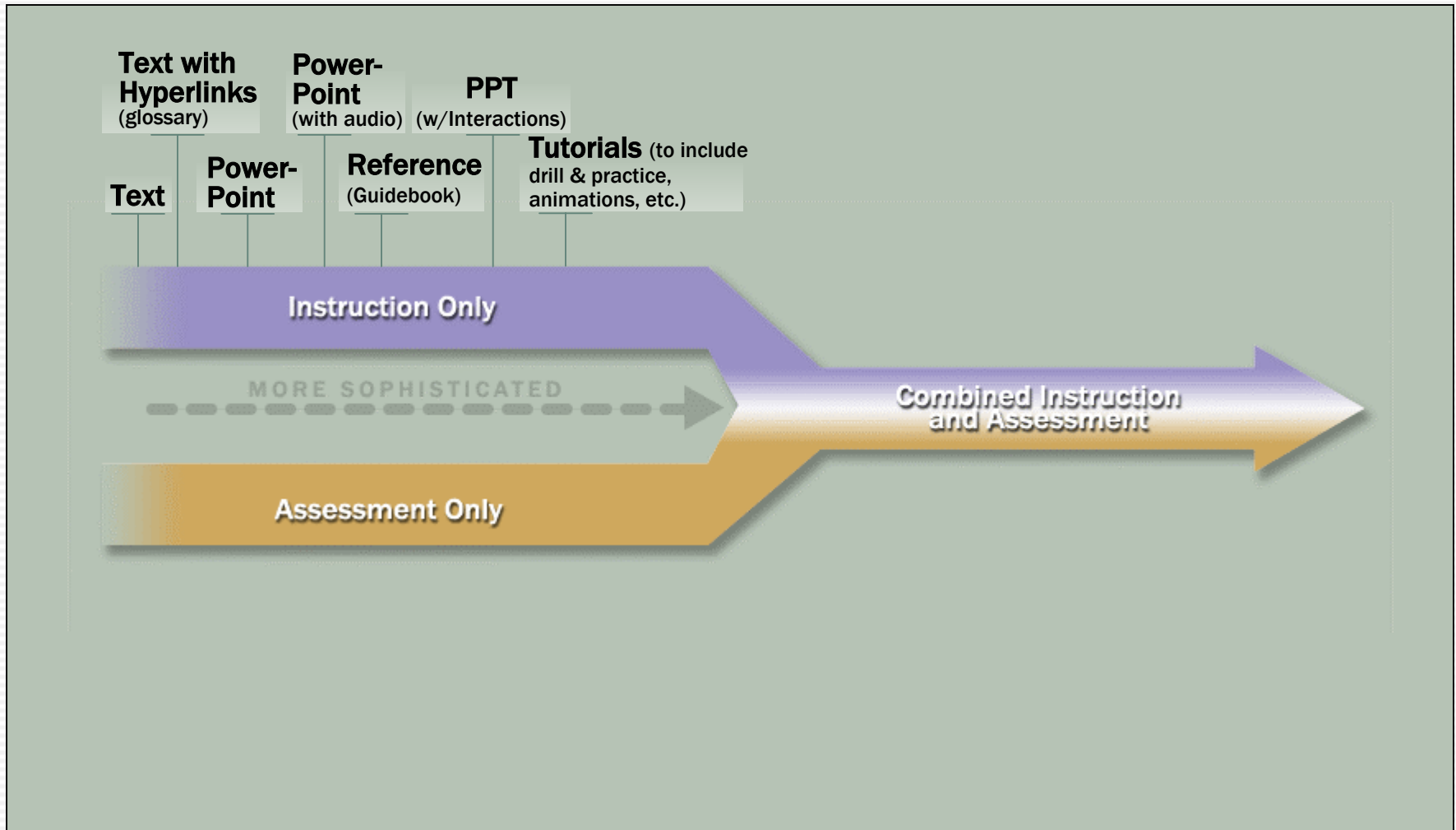


LearnWright's e-Learning Approach

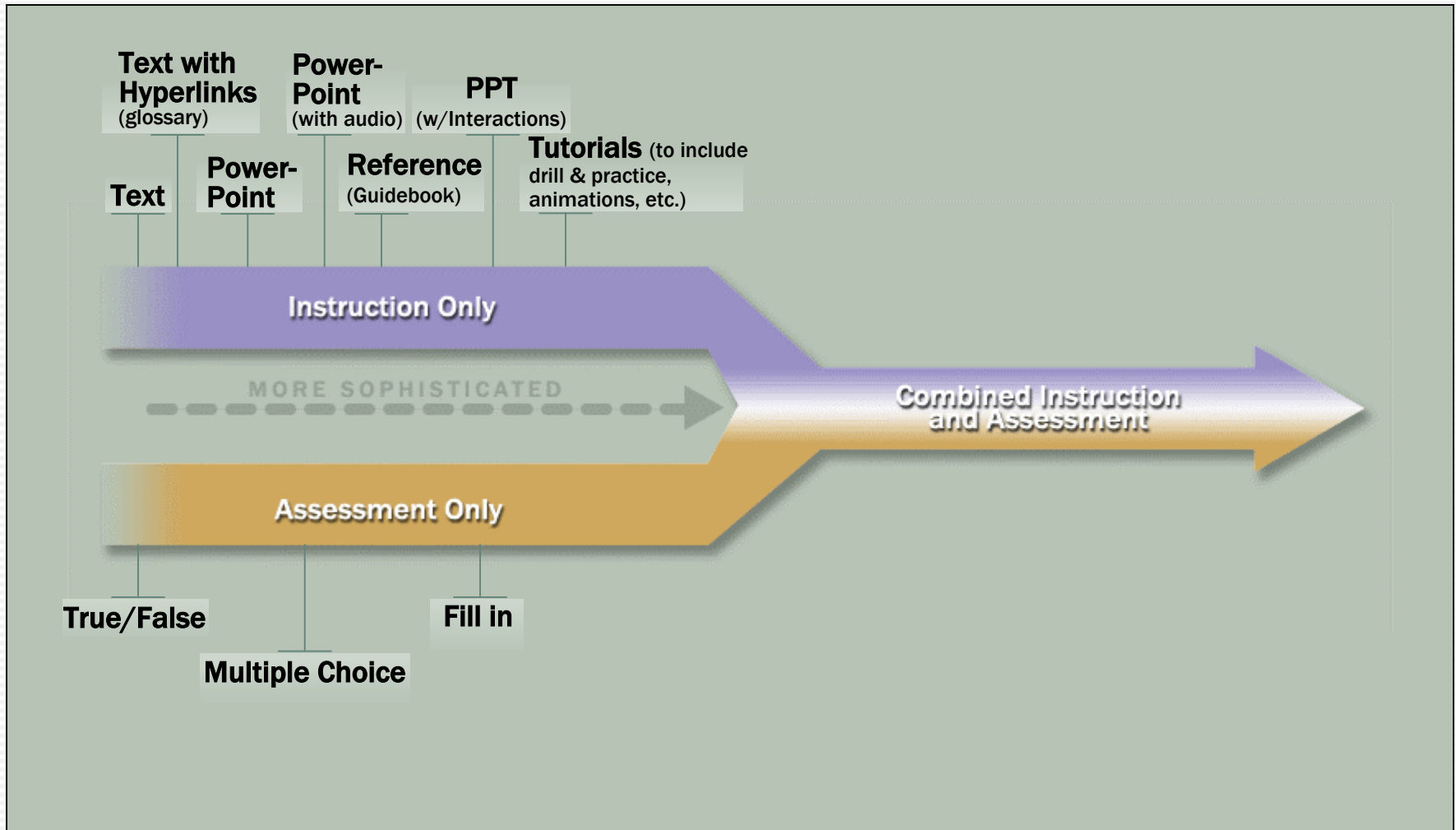
LearnWright uses the best, most appropriate, and innovative “**Models of Instruction and Assessment**” based on specific training needs.



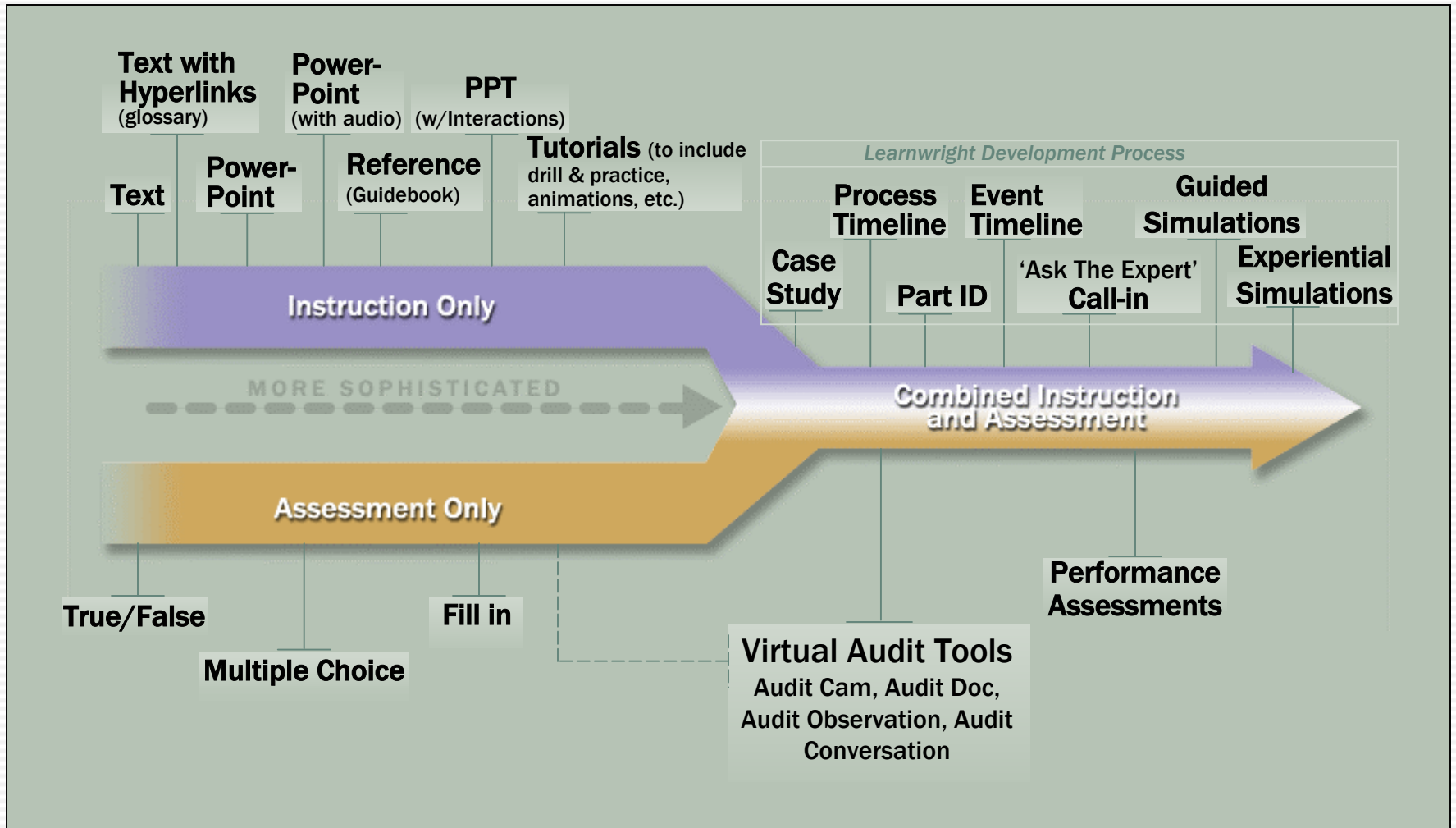
Traditional Computer-Based Training Models



Traditional Computer-Based Training Models



LearnWright's Evolving Models of Instruction and Assessment





Assessment: Guiding Principles

- If it is not assessed, it hasn't been learned.
- The closer the assessment tool is to how the job is performed, the more valid the assessment is as a predictor of how the person will perform on the job.
- Reliable, valid, and authentic assessments serve multiple purposes.
- Another unique characteristic of LearnWright's assessment strategies is that they are carefully aligned with, and sometimes blended into, the models of instruction.

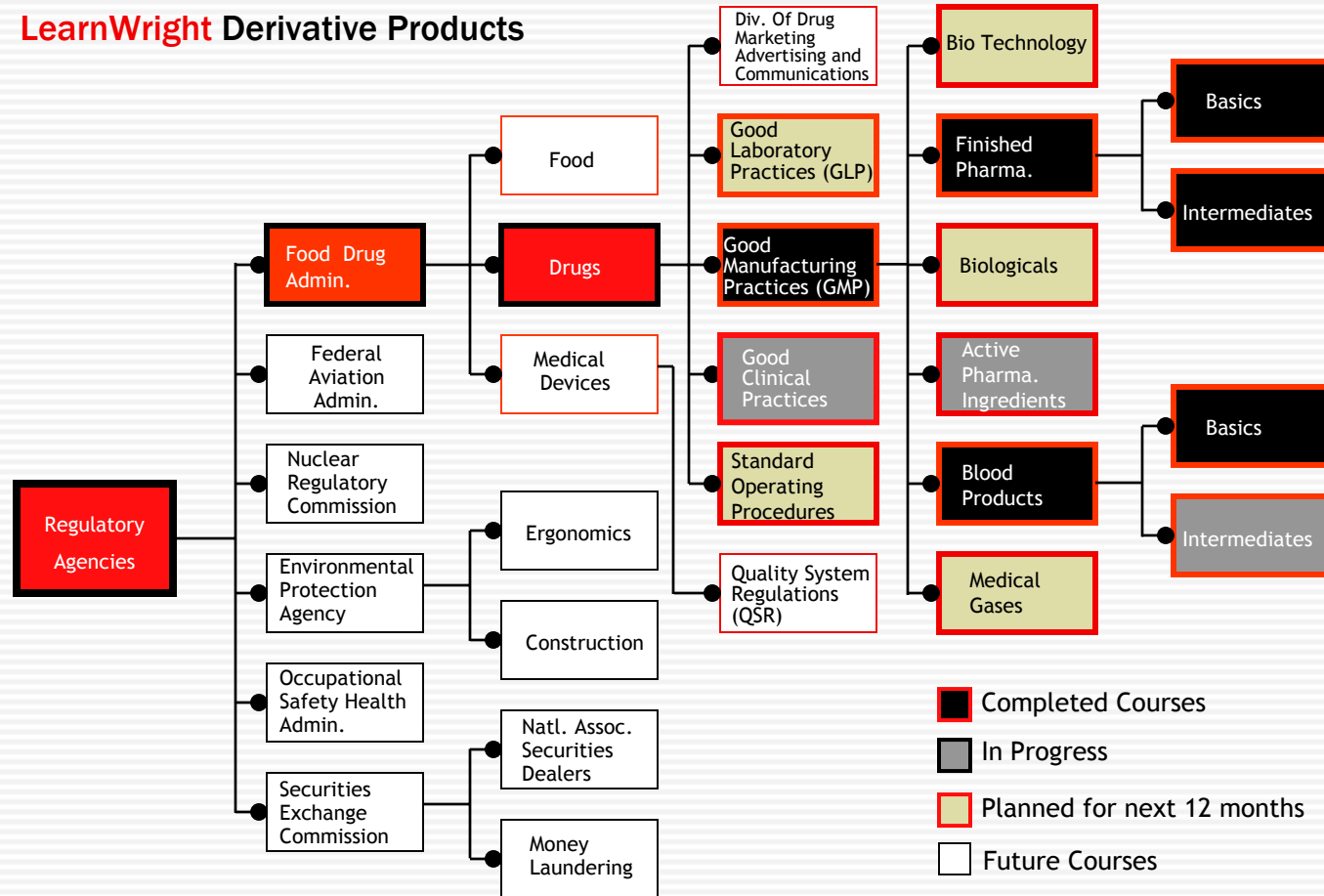


Assessment: Guiding Principles

Ultimately, the success of an e-learning program depends upon the alignment of its assessment tools with objectives, content, tasks, and technology.

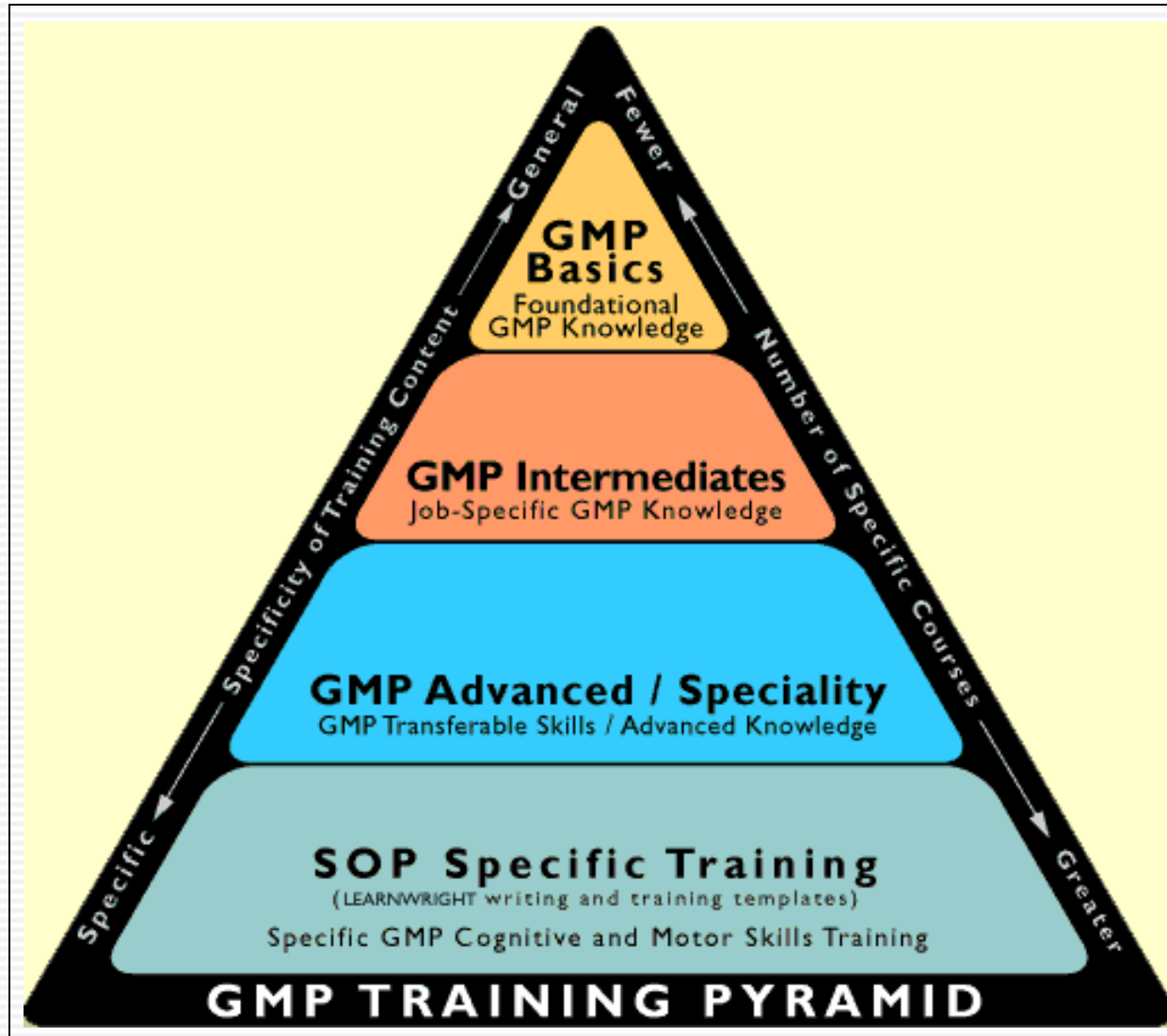
LearnWright Markets

LearnWright Derivative Products



Examples of US regulatory agencies and the industries they regulate -- all of which are candidates for LEARNWRIGHT course production.

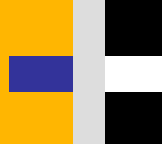
GMP Training Pyramid





HIPAA Privacy and Security Training

- *Basics* of Good Privacy and Security Practices
 - Introduction to HIPAA
 - Who Must Comply
 - Privacy Compliance
 - Individual Rights
 - Permissible Uses
 - Permissible Disclosures
 - Security Compliance
 - Administrative Procedures
 - Physical Safeguards
 - Technical Security Services
 - Technical Security Mechanisms



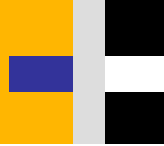
HIPAA Privacy and Security Training

- *Intermediate* Privacy and Security Practices
 - Security
 - Approximately 80 rules in depth.
 - Privacy
 - Detailed policies and procedures
 - General
 - *More stringent* state privacy rules
 - Permissible uses
 - Permissible disclosures
 - Availability
 - Basic March 2003
 - Intermediate August 2003



GMP for FPP Job/Task Matrix

Task	Position									
	Code	Warehousing, distribution	Facility Cleaning	Mfg - dispensing	Mfg - operator	Filling/Pkg and Labeling	QC lab analyst	QA Rep	Tech Support	Maintenance Pers Engineering
Aseptic Technique	AT				X	X		X	X	
Change Control	CC	X	X	X	X	X	X	X	X	X
Clothing & Personal Hygiene	CH	X	X	X	X	X	X	X	X	X
Discrepancy Observation/Investigation	DO	X	X	X	X	X	X	X	X	X
Documentation and Recordkeeping	DR	X	X	X	X	X	X	X	X	X
Equipment Cleaning	EC			X	X	X		X		X
Equipment	EQ	X		X	X	X	X	X	X	X
Facility & Support Systems	FS	X	X	X	X	X	X	X	X	X
Identity Control	ID	X		X	X	X	X	X		X
In-process Controls	IC				X	X	X	X	X	
Lab Activity 1: Lab Operation	L1						X	X		
Lab Activity 2: Sample Preparation & Analysis	L2						X	X		
Label Control	LC					X		X		
Line Clearance	LR					X		X		X
Maintenance and Repair	MA		X					X		X
Materials Receiving	MR	X		X	X	X		X		
Quality Operations	QO							X		
Sampling	SP				X	X	X	X		
Sanitation (housekeeping)	ST	X	X	X	X	X	X	X	X	X
Storage and Distribution Practices	SD	X						X		
Training	TR	X	X	X	X	X	X	X	X	X
Validation	VL	X	X	X	X	X	X	X	X	X
Weighing and Dispensing	WD			X				X		



LearnWright's **Models of Instruction**

Tutorials

Presentations (Informational Style)

Reference

Assessment

Admin Tools



LearnWright's **Models of Instruction**

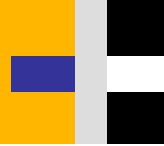
Tutorials

- Game Show
 - **Orientation**
- Timeline
 - **History** (How We Got Where We Are Today)
- Characteristics
 - **The Essential Elements and Characteristics**
- Regulatory Overview
 - **Regulatory Development / Structure / Application**
- Results of Non-Compliance
 - **Case Study in Pain**
- Expectations
 - **What to Do?**
- What it Means to Me
 - **Personal Action Plan**

LearnWright's **Models of Instruction**

Presentations

- Slide Show
 - **PowerPoint Style**
- A /V Slideshow
 - **Autoplay**

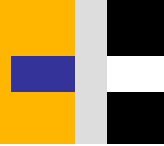


LearnWright's **Models of Instruction**

Reference

- Guidebook

- **Expectations-** Concise overview of what you need to know in the regulations.
- **Details-** Detailed explanation of expectations.
- **Regulatory References-** Excerpts from regulations supporting the expectations.
- **Personal Comments-** Case study highlights through AV clips.
- **Guidebook-** AV overview of topic.



LearnWright's **Models of Instruction**

Assessment

- Audit Doc
 - **What is wrong with this document** (Graphic depiction of problems with a document)
- Audit Cam
 - **What is wrong with this picture/video** (Video depiction of person(s) performing job incorrectly)
- Audit Observation
 - **Find the matching regulatory reference to the agency offense**
- Audit Conversation
 - **What is wrong with this conversation/discussion** (Audio depiction with supporting dialog script of problems with conversation between two people)
- Multiple Choice Test



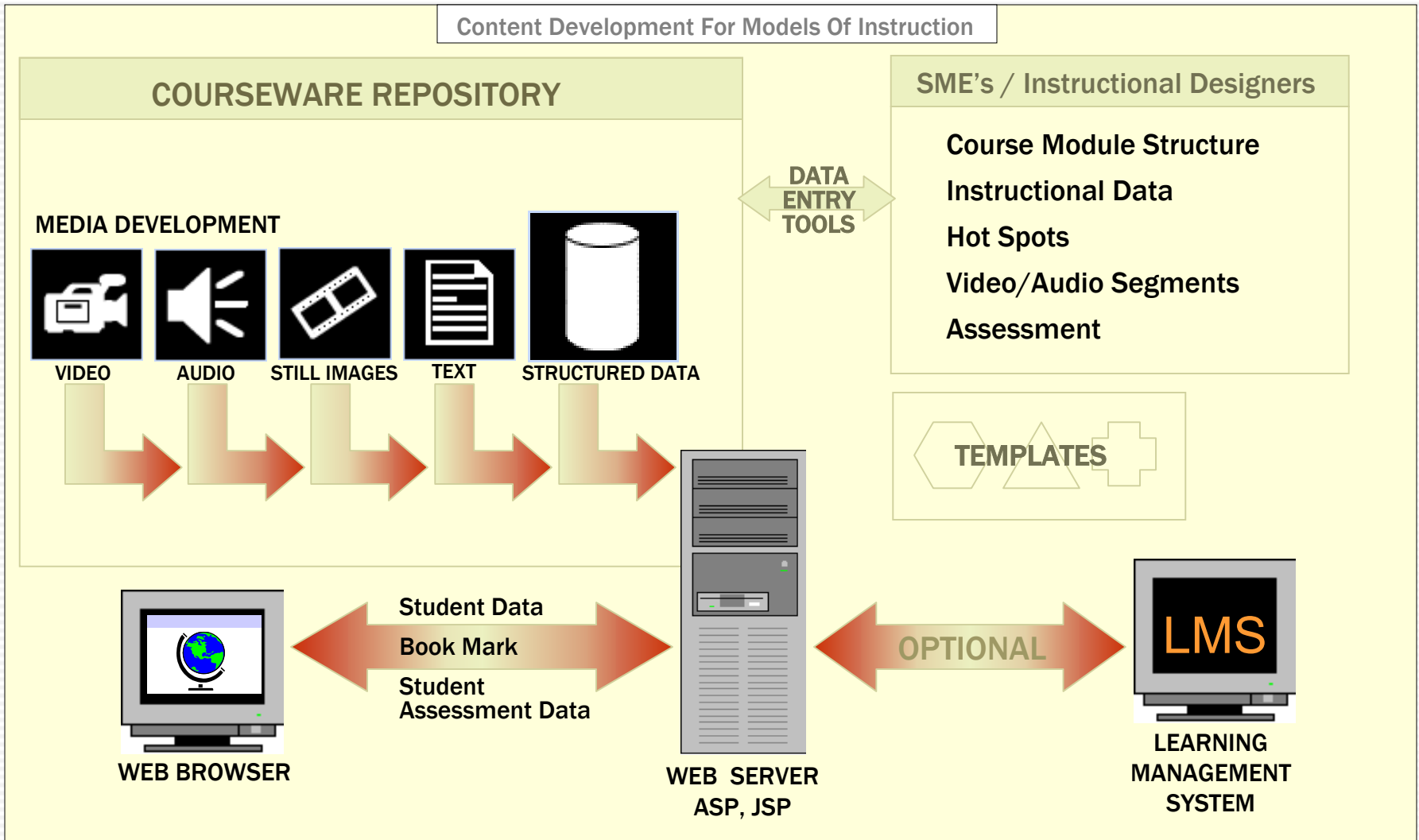
LearnWright's **Models of Instruction**

Admin Tools

- Coursemap



Courseware Development Tools





Models of Instruction Software Implementation

Courseware Development Tools

Module Content Development

Presentation

Interface to External Corporate Systems



Models of Instruction Software Implementation

Courseware Development Tools

- **Expensive, time-consuming to develop.**
- **Combine:**
 - **Conceptual models of instruction**
 - **Database design**
 - **Software design**
 - **Active Server Pages, JavaServer Pages, HTML/DHTML, JavaScript, VBScript**
 - **Support both Oracle and Microsoft SQL Server**
- **Essentially a one-time cost; will be expanded over time.**
- **Tested, developed, QA'd.**
- **Once developed, each model is easily adapted to new course content material.**



Models of Instruction Software Implementation

Module Content Development

- **Economies of scale.**
- **SME's and Instructional Designers create content using LearnWright's Models of Instruction.**
- **Rich Media**
 - **Video**
 - **Audio**
 - **Still Images**
 - **Text Data**
 - **Structured data consisting of:**
 - Course Module Structure
 - Instructional content
 - Video, audio segments
 - Tutorial and explanatory text
 - Hotspot areas
 - Questions / Answers /Distractors
 - Student personnel data, bookmarks, assessment data
- **Toolsets reduce problem of creating new courseware to a data entry project.**
- **Relational Database is heart of system.**



Models of Instruction Software Implementation

Presentation

- **Web server-based system.**
- **Follows standard n-Tier system: data tier, business rules / middle tier, presentation tier.**
- **Can be hosted in corporate intranet, inside firewall, or in data center accessed via Internet.**
- **Middleware: ASP, JSP/Servlets run on web server, access database and deliver content to user.**
- **User logs in, is authenticated in database via Web server.**
- **Content is delivered to user's browser through ASP/JSP/ Servlets.**
- **Client-side plug-in: Marcomedia Shockwave plus streamed video.**



Models of Instruction Software Implementation

Interface to External Corporate Systems

- A standardized interface (AICC, SCORM, others) exists for Learning Management Systems (LMS).
- Supporting company's existing LMS helps to launch courses and return scores back to LMS.
- 21 CFR Part 11 is an important Federal regulation relating to handling of electronic records and electronic signatures (ERES); Stringent requirements deal with handling data.
- At BMS, we have interfaced our system's login authentication to their existing single-sign-on system based on LDAP
- At AstraZeneca our system is interfaced to their Plateau LMS implementation.

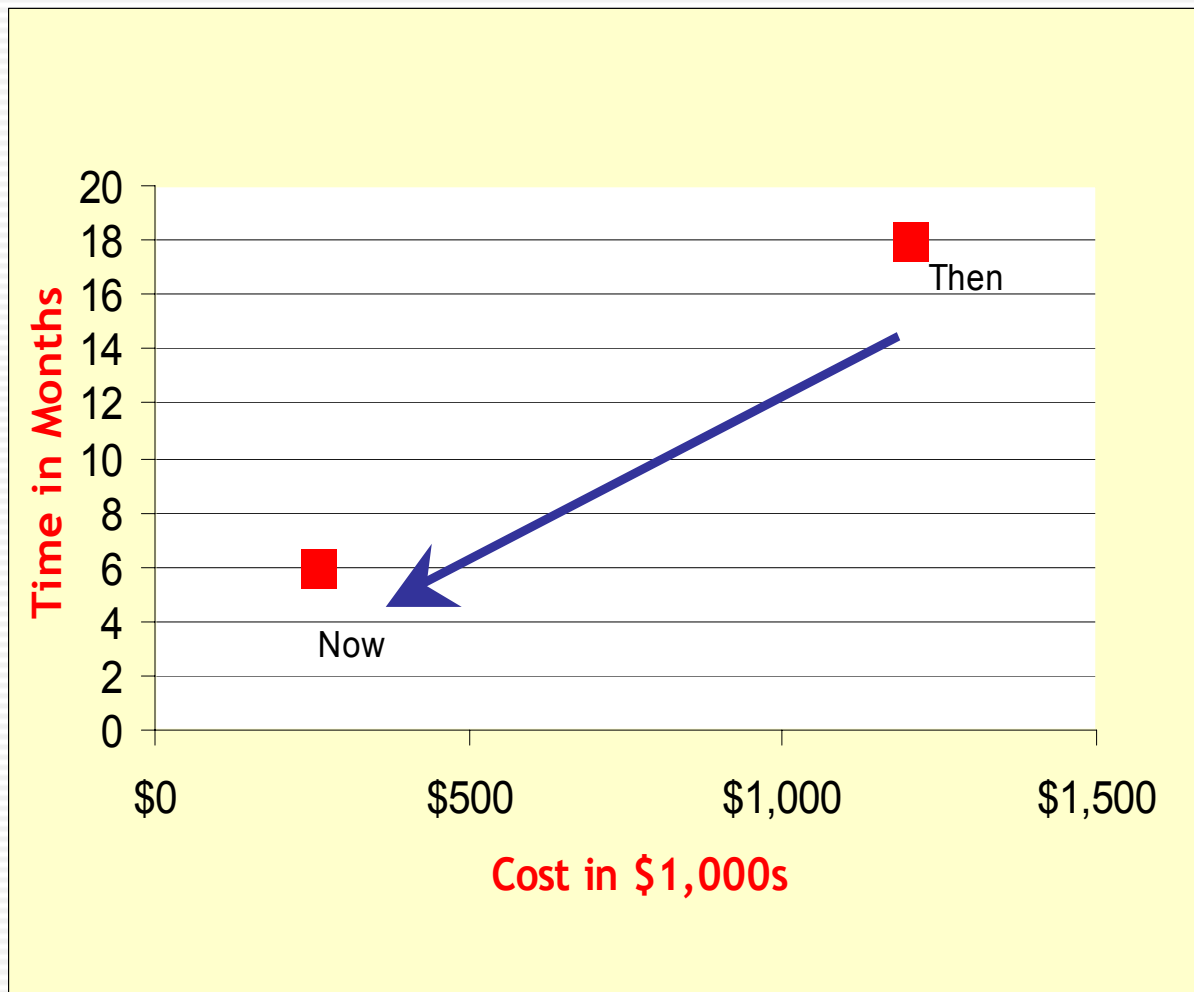


e-Learning Advantages

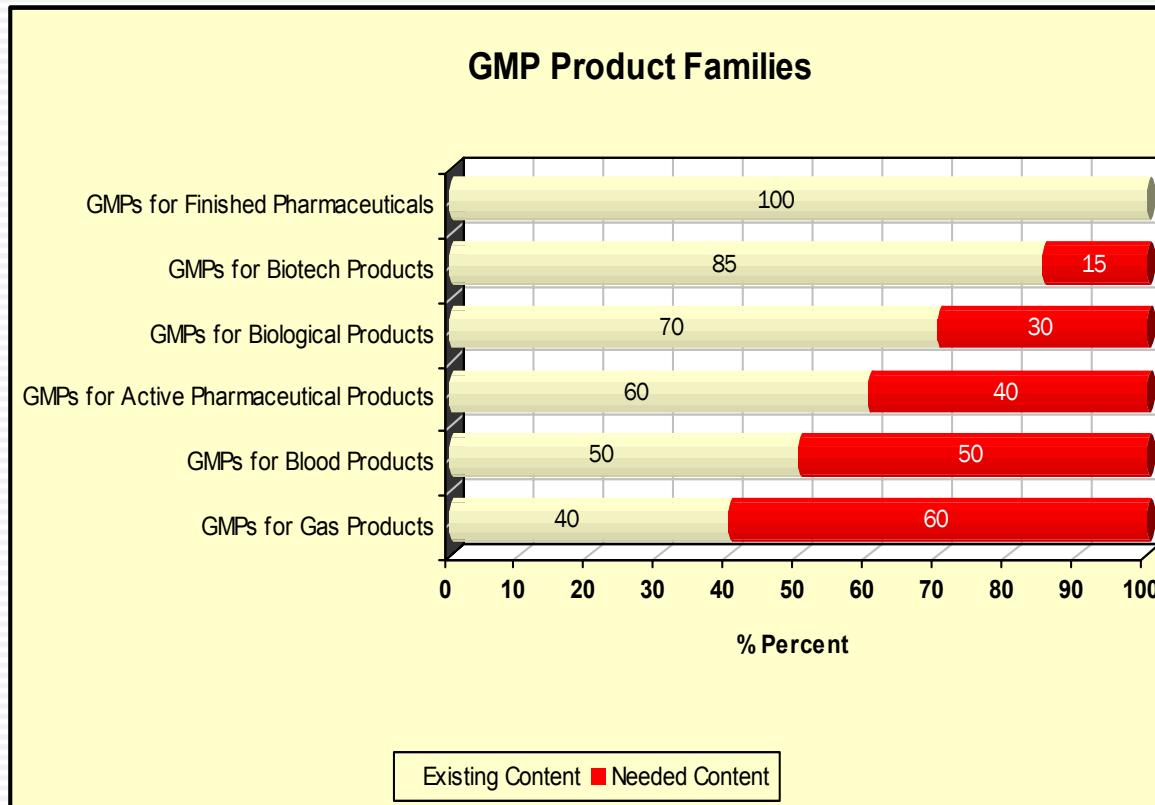
- **Content Consistency – everyone gets same message.**
- **Training-On-Demand - 7 x 24.**
- **Reduces Travel - save time and money.**
- **Training is Current - course content is updated and available immediately.**
- **Standardized Delivery – browsers/executables.**
- **Self-Paced – students progress at their own rate.**
- **Matches Employee Profile.**
- **Centralized Record Keeping System.**
- **Course content can be customized to meet specific needs.**
- **Augments Trainer Role.**
- **Comprehensive Multiple Language Support possible.**



New Product Time and Cost Efficiency

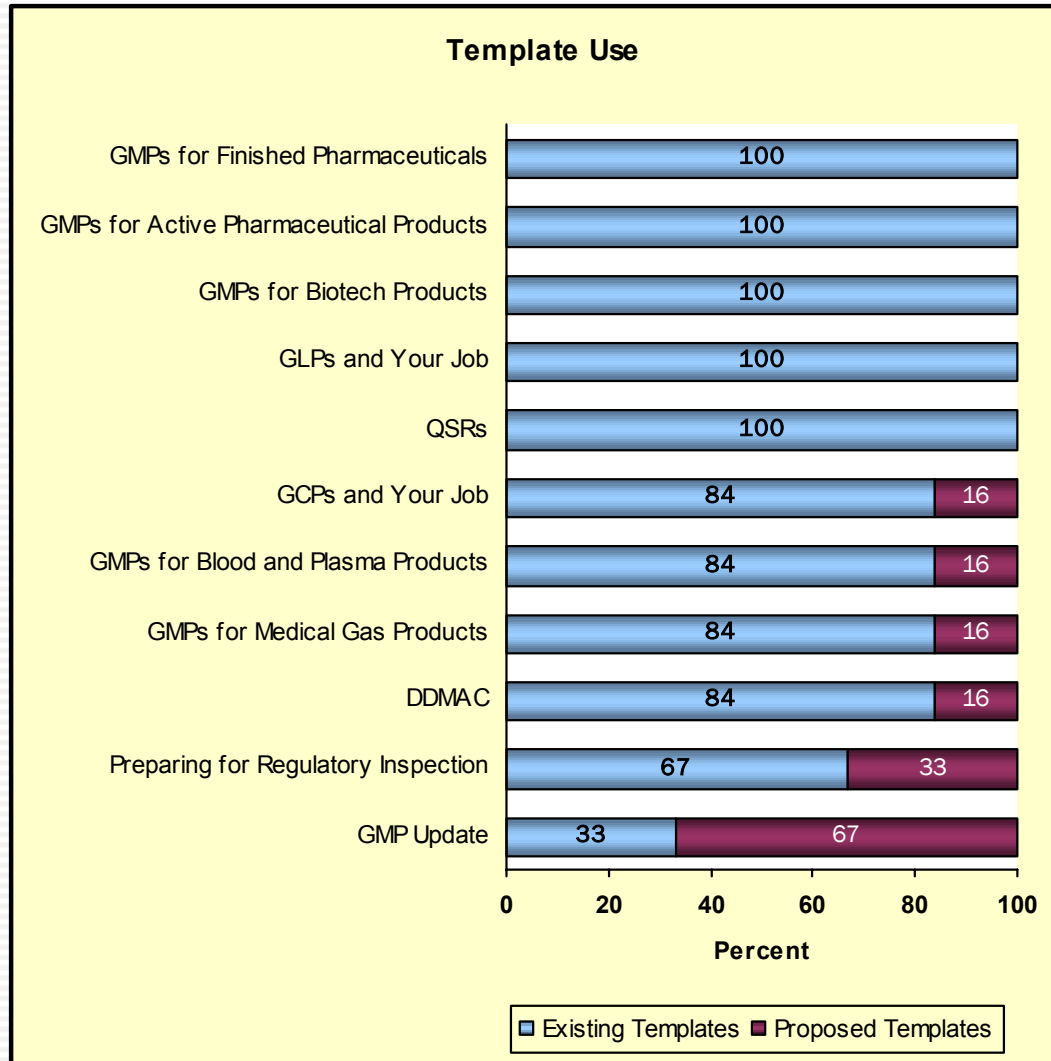


Scalability Through “Repurposed” Content



Cascade of the GMP (Good Manufacturing Practices) near-neighbor courses, beginning with *Finished Pharmaceuticals* already completed, showing relative percentages of re-usable and new content required for each.

Scalability Through Reapplied Templates





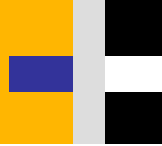
Model/Template Types

- **Presentational**
 - Tutorials
 - E.g., Course Intro
 - A/V Presentations (Slide Show Format)
 - E.g., Guidebook Tour
- **Referential**
 - Database Forms
 - E.g., GMP Guidebook
- **Evaluative**
 - Audit Document (What's wrong with this document?)
 - Audit Cam (What's wrong with this picture/video?)
 - Audit Conversation (What's wrong with this interaction?)
 - Audit Observation (Here's the citation, what's the Reg?)
- **Scaffolded Practice (Future)**
 - Guided Learning
- **Experiential (Future)**
 - Simulation Based



LearnWright's Approach for New Projects

- **Analyze, including**
 - Purpose/goal
 - Content
 - Audience
 - How assessment will be used
 - Technology available now / near-term
- **Proposed solutions and detailed budget**
- **Detailed design and functional requirements**
- **Development**
 - Initial (including QA/user testing)
 - Continued
- **Implement (including qualifications)**
- **Evaluate**
- **Revise**



Alliances/Partners

- Content Providers
 - LearningPlus
 - American Red Cross (BPP)
 - MEDEX (GCPs)
 - Lonzagroup (APIs)
 - Others to be added as needed
- AstraZeneca
- University of Georgia: Dept. of Educational Technology
- Plateau Systems



Information Sources

o Training

- U.S. Department of Health and Human Resources (HHS)
 - www.aspe.hhs.gov/admnsimp
- Center for Medicare and Medicaid Services (CMS)
 - www.cms.hhs.gov/hipaa
- Office for Civil Rights (OCR)
 - www.hhs.gov/ocr/hipaa/
- Workgroup for Electronic Data Interchange (WEDI) and WEDI's Strategic National Implementation Process (SNIP)
 - www.wedi.org www.snip.wedi.org

o LearnWright

- www.learnwright.com



Questions

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