

SoCalBio Regulatory Workshop



Regulatory Inspection Techniques and Best Practices

Julie Finke



Regulatory Inspection Management

- Why strive for Excellence?
- Stay in business!
- Good reputation with regulatory agencies
- Required for certain markets
- Faster submission approvals
- Fewer observations
- Minimize impact on operations
- Less stress

Results

- Inspection Room ready in minutes!
- Reduced request entry and tracking cycle time by 83%
- Manage hundreds of audit requests accurately!
- Audit request status available in real time!
- Reduced observations per inspection day by 38%
- Recognized Division Best Practice



Results (cont.)

- Reduced FDA 483 observations by 82%
- “Preparation was very good and the process was very efficient” - Corporate auditor
- “Pro-active and professional, appreciate getting documents in a rapid fashion, continue to do a good job, very positive experience” - FDA Lead Investigator
- Quality Operations Award Winner – Inspection Management



Inspection Management Excellence



Preparation

Inspection Committee

- 3 months prior to anticipated inspection
- Cross-functional
- Routine Meetings
- “Dirty Dozen” (or other top issues)
 - Focus, focus, focus!
- Previous observations and commitments
- Inspection Preparedness Protocol/Checklists/SOPs

Preparation

Leadership Focus/Visibility

- Walk Abouts
- “Rust Busters”
- Link with Facilities/Engineering

Training

- Balance: What and how much to say
- Practice Sessions/Role Play
- Match experience with less experience

Preparation

Opening Presentation

- Update Content
 - Business, Products and Site History
 - Organization
 - Product Manufacturing Processes
 - Facilities
 - Significant Changes
 - Significant Projects
- Ready 24/7
 - Flash drive, central location
- Identify presenters

Preparation

Logistics

- Define roles and responsibilities
 - Inspection and Preparation rooms
- Contact Information - Subject Matter Experts
- Inspection and Preparation Room supplies staged
- Mock Set Up Sessions
- Lists
 - Complaints
 - Investigations
 - Change Control Requests
 - OOS

Preparation

Audit Response Tracking

- Electronic tracking
- Audit Utopia
- Instant reporting
- Status for debrief sessions



Preparation

Audit Utopia



The image shows a computer monitor displaying the 'auditUTopia' website. The website has a dark header with the logo 'auditUTopia' in white and red. Below the header is a navigation bar with links: 'CONFERENCE ROOM', 'DUGOUT', 'AUDIT REQUEST REPORT', 'POST AUDIT ISSUE', and 'EXIT'. A 'Welcome Steve Kim' message is visible. The main content area features a 'WELCOME!' section followed by an 'Abstract' paragraph. At the bottom of the website, there are links for 'CONTACT US', 'PARTNER', and 'USEFUL LINKS', along with a copyright notice for '© 2006 Pharmaceutical Services Corporation'. The background of the monitor shows a desk with stacks of papers and a coffee cup. Below the monitor, the 'auditUTOPIA' logo is repeated in a larger font, with the tagline 'Control of Quality Audits.' underneath. To the right of the logo is a login form titled 'LOGIN TO AUDITUTOPIA' with fields for 'USERNAME:', 'PASSWORD:', and 'DUGOUT:' (with a dropdown menu set to 'YES'). There are 'Login' and 'Cancel' buttons at the bottom of the form.

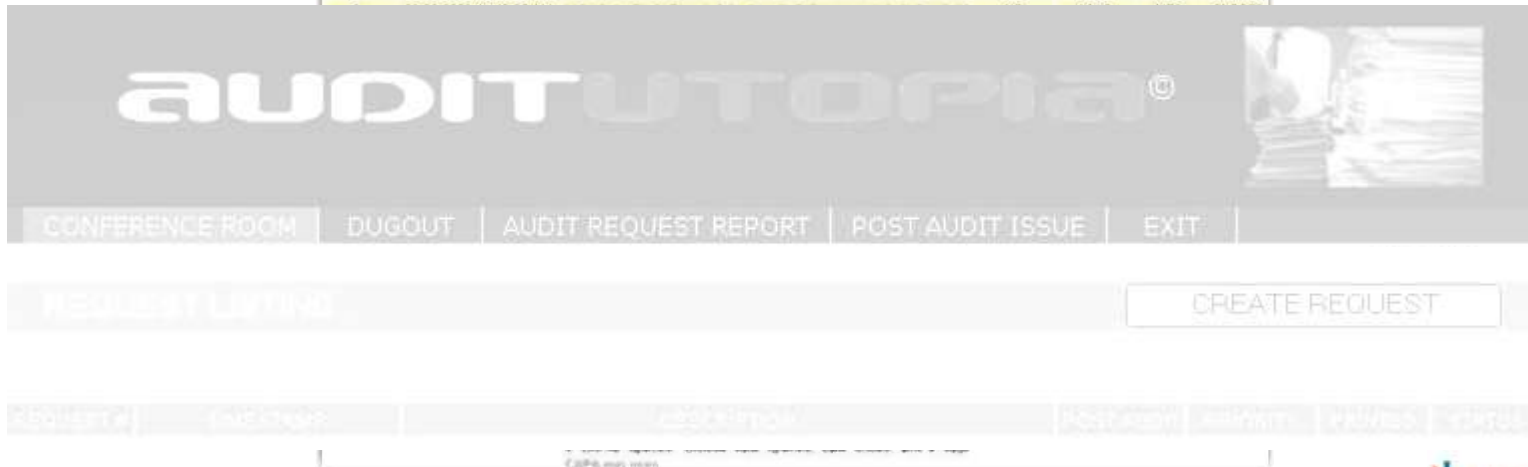
Preparation

Audit Utopia



The screenshot shows the Audit Utopia web application interface. At the top, there is a navigation bar with the following menu items: CONFERENCE ROOM, DUGOUT, AUDIT REQUEST REPORT, POST AUDIT ISSUE, and EXIT. Below the navigation bar, there is a header section with the text "REQUEST LISTING" and a "CREATE REQUEST" button. The main content area displays a table with the following columns: REQUEST.#, TIMESTAMP, DESCRIPTION, POST AUDIT, PRIORITY, PRINTED, and STATUS. The table contains 8 rows of data, all with a status of "CLOSED".

REQUEST.#	TIMESTAMP	DESCRIPTION	POST AUDIT	PRIORITY	PRINTED	STATUS
1	09-09-2008 11:30:48 AM	Medi award OLA submission to agency	NO	ASAP	YES	CLOSED
2	09-09-2008 11:30:55 AM	Medi award OLA submission to agency	NO	ASAP	YES	CLOSED
3	09-09-2008 11:32:12 AM	List of CRO activities, status and available brief description of exception and indicated action and audit level. Specify facility type of exception identified include investigation to resolve OPA/EE. List to be created to include type of water (purified, potable, WFI) instead of just number	NO	ASAP	YES	CLOSED
4	09-09-2008 11:33:33 AM	List of water sensitive Divertible Organism and count brief description OPA/EE. List to be created to include type of water (purified, potable, WFI) instead of just number	NO	ASAP	YES	CLOSED
5	09-09-2008 11:34:44 AM	List of all test methods used for release and if they are validated/qualified	NO	ASAP	NO	CLOSED
6	09-09-2008 11:35:43 AM	List of all change control and Change Control procedure done December 2008	NO	ASAP	NO	CLOSED
7	09-09-2008 11:37:08 AM	List of equipment used of non dedicated equipment, not multiple	NO	ASAP	YES	CLOSED
8	09-09-2008 11:38:45 AM	SOP to batch release Test copies of OLA-048, 04923, 04929	NO	ASAP	NO	CLOSED



Execution

Inspection Room

- Audit Oversight
- Chat Room
 - Real time communication between inspection room and preparation room
- Investigator Support Teams
 - Escort
 - Assistant/Coordinator
 - Scribe
 - Electronic Request Tracking System
 - Runners (Training opportunity)

Execution

Inspection Room

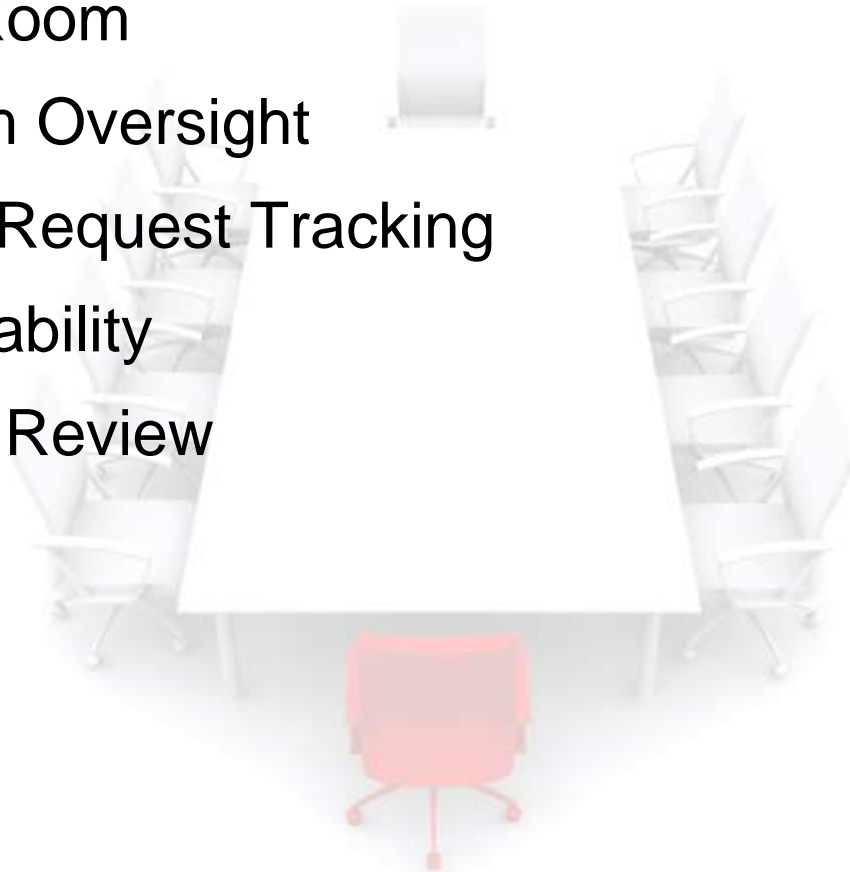
- **Investigator Discussions**
 - Teams of Subject Matter Experts
 - Experienced and trained
 - Anticipate and be prepared
- **Request Daily Wrap Up Sessions**
 - Identify items that require follow-up



Execution

Preparation Room

- Prep Room Oversight
- Electronic Request Tracking
- SME Availability
- Document Review



Execution

Internal Daily Debrief Meetings

- Review request status
- Assign teams to key open issues
- Plan next day logistics
 - Timing
 - Ensure presenters are ready and available



Post Audit

Response Preparation

- Identify Subject Matter Experts
- Compliance Assistance
 - Assign for key/complex issues
- Balance
 - Speed with thoroughness
- Observation Response
 - System evaluation
 - Root cause assessment
 - Corrective actions
 - Specific observation corrections
 - Supporting evidence



Post Audit

Response Execution

- Maintain response completion evidence centrally
- Consider routine updates on progress

Inspection Report (Establishment Inspection Report)

- Evaluate for additional commitments
- Assign additional actions as needed

Continuous Improvement

- Internal lessons learned/debrief session
- Incorporate feedback

Summary

Successful Inspection Management

- First Impressions are Important
- Preparation
 - Demonstrates organization and competence
- Execution
 - Timing and flow of information is key
 - Stay calm!
- Post Audit
 - Well researched and thoughtful responses
- Inspection Management Excellence leads to Results!

