

ii4sm  
healthcare ► context ► value

International Institute **for** the Safety of Medicines

**QIX**  
Quality Information Exchange

An illustration of how quality information can be integrated across organisations

October 13, 2010

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# What is the Quality Information Exchange (QIX)



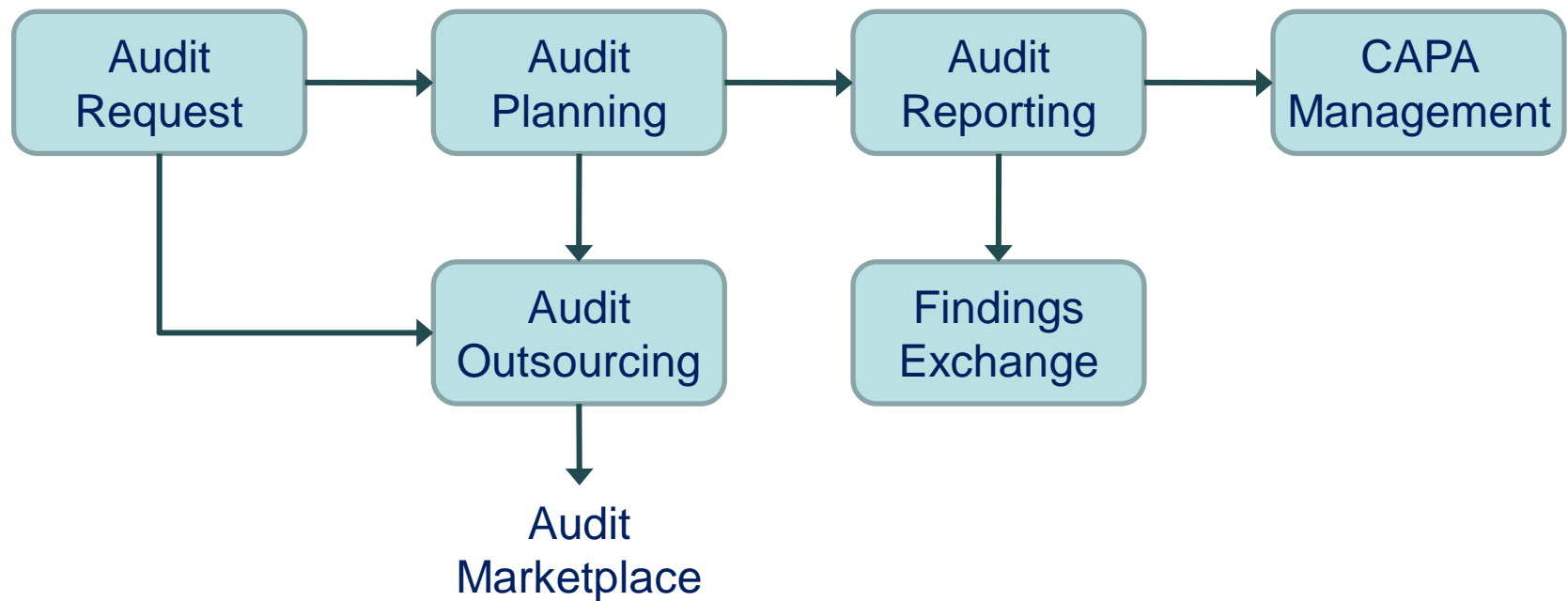
The Quality Information Exchange (QIX) is a suite of tools and services to enable research organisations to collaborate effectively with their partners and each other

- Quality Information Exchange is the ability to jointly exchange information about
  - (Audit) scheduling and planning
  - (Auditor) performance, auditee feedback and service level of service providers
  - Findings, including positive ,non-findings‘ to create a quality baseline
  
- Exchange of GCP QA information enables
  - Better scheduling, planning and targeting of audits
  - Risk baseline specification, benchmarking and objective comparison of performance
  
- This presentation is an example and illustration of
  - How operational data for risk management in GCP QA can be captured and shared
  - The example is focussed on transactional and performance data not medical content
  - The principles illustrated here can be applied to a broad set of trial planning activities

# QIX Software Module Overview



QIX software modules complement each other and offer operational flexibility to suit individual organisational needs and extensibility to include new data sources



The software is available as a hosted service so that users can access it worldwide, eliminate maintenance and enable the coordination of activities and mapping of data

# Creating Audit requests



Collecting and managing audit requests already creates valuable risk information and helps to focus QA resources more effectively

Quality Information Exchange



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[QIX Home](#) > [Audit Request](#) > Create Audit Request
[Log Out](#)

Home

Audit Request

Audit Planning

Audit Marketplace

Findings Exchange

Name: ORGA.PM  
Org: COMPANYYA  
Login At: 14:28

### Create Audit Request

Audit ID	
Audit Type	--Audit Type--
Audit Category	--Audit Category--
Priority	--Priority--
Auditee	
Location	Please Select Auditee First
Start Period	Sep - 2010
End Period	Sep - 2010
Duration (Days)	
Scope	
Objective	

Home

Audit Request

Audit Planning

Audit Marketplace

Findings Exchange

Name: ORGA.PM  
Org: COMPANYYA  
Login At: 14:28

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Quality Information Exchange



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[QIX Home](#) > [Audit Request](#) > Review Audit Request
[Log Out](#)

Home

Audit Request

Audit Planning

Audit Marketplace

Findings Exchange

Name: ORGA.PM  
Org: COMPANYYA  
Login At: 14:28

### Pending Audit Requests

Auditee	Category	Start Period	End Period	Duration	Region	Audit ID
Pharma Research Unit	Preinspection	Okt, 2010	Okt, 2010	2 Days	North America	<a href="#">A0004</a>
Pharma Research Unit	Preinspection	Okt, 2010	Okt, 2010	3 Days	North America	<a href="#">A0005</a>
Pharma Research Unit	Preinspection	Okt, 2010	Okt, 2010	5 Days	North America	<a href="#">A0006</a>
Pharma Research Unit	ForCause	Sep, 2010	Sep, 2010	5 Days	North America	<a href="#">A0007</a>
Global CRO	Routine	Sep, 2010	Sep, 2010	3 Days	North America	<a href="#">A0101</a>
Global CRO	Routine	Okt, 2010	Okt, 2010	5 Days	North America	<a href="#">A999</a>

### Audit Request Summary

Filter By: Category (All) Regions (All) Status (Any)

Auditee	Category	Start Period	End Period	Duration	Region	Status	Audit ID
Pharma Research Unit	ForCause	Sep, 2010	Sep, 2010	5 Days	North America	Approved	<a href="#">A0001</a>
Ultra sound facility	Routine	Sep, 2010	Sep, 2010	3 Days	North America	Approved	<a href="#">A0002</a>
Ultra sound facility	Routine	Sep, 2010	Sep, 2010	5 Days	North America	Approved	<a href="#">A0003</a>
Pharma Research Unit	Inspection	Okt, 2010	Okt, 2010	4 Days	North America	Approved	<a href="#">A0008</a>
Pharma Research Unit	ForCause	Sep, 2010	Sep, 2010	3 Days	North America	Approved	<a href="#">T001</a>
	Routine	Okt, 2010	Okt, 2010	0 Days		Approved	<a href="#">asr22</a>
	ForCause	Nov, 2010	Nov, 2010	0 Days		Approved	<a href="#">asr26</a>
Pharma Research Unit	ForCause	Sep, 2010	Sep, 2010	2 Days	North America	Approved	<a href="#">a444</a>
CompanyA	Inspection	Sep, 2010	Sep, 2010	3 Days	Europe	Approved	<a href="#">A555</a>

# Audit Planning



Packaging audits and creating checklists enables audit planners to specify the focus and details that need to be audited in a structured and standardised way

## Quality Information Exchange

### Packaging Wizard

Organizations	CompanyA,
Regions	Europe, North America,
Audit Categories	ALL
Audit Types	CRO / SMO, CPU,
Audits Returned	2

### Select Audit(s) And Click Next To Continue

Organization	Region	Audit Category	Audit Type	Objective	Scope	Rationale	
CompanyA	North America	ForCause	CRO / SMO	Objective for Audit: A0001	Scope for Audit: A0001	Rationale for Audit: A0001	<input type="checkbox"/>
CompanyA	North America	Routine	CPU	Objective for Audit: A0008	Scope for Audit: A0008	Rationale for Audit: A0008	<input type="checkbox"/>

## Quality Information Exchange



[QIX Home](#) > [Audit Reporting](#) > [Create Audit Checklist](#) > Create Audit Checklist

[Log Out](#)

Name: ORGAIA  
 Org: COMPANYA  
 Login At: 14:50

### CheckList

Audit Type	System	Process	Deliverable	
CPU	Business Management	Accreditation	Record/Document	<a href="#">Delete</a>
CPU	Business Management	Approval	Agreement/Contract	<a href="#">Delete</a>
CPU	Business Management	Change Control	Process	<a href="#">Delete</a>

# Structuring Findings (and 'non-findings')



The audit report findings 'grid' enables like-for-like comparisons between findings and for organisations to map findings to a common meaning

QCM Home > Audit Reporting > Write Audit Report > Write Audit Report  Log Out

Home    General    Scope    Audit Activities    Findings    Report Summary    CAPA

**Findings**  Finalized

Audit Type	System	Process	Deliverable	Findings Class	Summary	
Laboratory ▼	Equipment ▼	Change Man. ▼	Plan and/or P. ▼	Minor ▼	Twoos in ...	Delete
Laboratory ▼	Facilities ▼	Contaminatio. ▼	Contingency P. ▼	Critical ▼	No ...	Delete
Laboratory ▼	Personnel ▼	Education/Tr. ▼	Record/Docu. ▼	Major ▼	No record ...	Delete

This also enables organisations to map their terms to a common environment and report on both negative 'findings' & positive 'non-findings' to create quality baselines

# Audit Report Writing and Findings Publication



Writing reports is facilitated as a large number of the fields are pre-populated and the findings can be published to designated partners

## Quality Information Exchange



[QIX Home](#) > [Audit Reporting](#) > [Write Audit Report](#) > Write Audit Report

[Log Out](#)

- Home
- Audit Planning
- Findings Exchange
- Audit Reporting
- Name: ORGA.IA  
Org: COMPANYA  
Login At: 14:50

- Information
- Overview
- Detail
- Findings
- CAPA

Audit ID	a444		
Start Period	Sep, 2010	End Period	Sep, 2010
Location	Chicago / USA	Duration (Days)	2
Priority	High	Audit Type	CRO / SMO
Category	ForCause		
Auditee	Pharma Research Unit		

## Quality Information Exchange



[QIX Home](#) > [Findings Exchange](#) > Publish Audit Findings

[Log Out](#)

- Home
- Findings Exchange
- Audit Reporting
- Name: ORGB.FP  
Org: COMPANYB  
Login At: 15:21

### Publish Audit Findings

Audit Id	Audit Category	Audit Type	Audit Priority	City	Country	# Findings	Action
A00012	Routine	CSV	High	Basel	Switzerland	2	<a href="#">Publish Findings</a>

Non-Published Findings for Audit Id:A00012

Audit Type	System	Process	Deliverable	Class	Has Findings	Is Proprietary	Summary
CSV	Equipment	Calibration	Acceptance Criteria	Minor	True	True	Acceptance criteria not defined.
CSV	Computer System	Back up/Retrieval	Procedure	Critical	True	True	No backup and recovery procedure in place.

# CAPA Management & Working with auditees



The findings matrix can be directly linked to CAPAs and mitigation actions with select access for auditees to propose edits for reports and CAPAs during the approval loop

[QCM Home](#) > [Audit Reporting](#) > [Write Audit Report](#) > Write Audit Report

[Log Out](#)

Home

Audit Planning

Findings Exchange

Audit Reporting

Name: ORGA.IA  
 Org: COMPANYYA  
 Login At: 10:08

General

Scope

Audit Activities

Findings

Report Summary

CAPA

## CAPA

Audit Type	System	Process	Deliverable	Findings Class	CAPA
Laboratory	Equipment	Change Manag	Plan and/or Re	Minor	Activate a <span style="color: green;">...</span>
Laboratory	Facilities	Contamination	Contingency Pl	Critical	Create and <span style="color: green;">...</span>
Laboratory	Personnel	Education/Train	Record/Docum	Major	Establish a <span style="color: green;">...</span>

## Selected Options

Audit Type	System	Process	Deliverable	Finding	Class
Laboratory	Facilities	Contamination	Contingency Plan	Yes	Critical

## CAPA

Create and implement a contingency plan by end of the year.

# Setting Trust Levels & Ensuring Confidentiality



Trust levels and role-based access ensure that only anonymous data specifically designated for release can be seen by others and access is actively granted

Quality Information Exchange

QIX Home > Trust Settings > Define Trust Settings Organization To Organization Log Out

Home

Findings Exchange

Trust Settings

Name: ORGA.FM  
Org: COMPANYA  
Login At: 15:00

Define Inter-Company Audit Sharing Trust Level

General Audit Sharing Level Chosen : **Level 4** ...

Organization	Your Setting	Their Setting
CompanyB	Level 4 ▾	Level 5

Agree to the [Terms & Conditions](#) of information sharing defined in the QIX Audit Findings Exchange Contract

Clear
Submit

Log Out

Level 4 ▾

where a different level has not been specified for a company

	Description
0	Use this as the default level if you do not wish to share any information * All information only for internal company users * Data can be used only by ii4sm for anonymized aggregated benchmarking and analysis
1	At Level 1 only the following information will be exposed: * Audit Location, Country & City * Audit Category
2	At Level 2 information from lower levels and the following information will be shared: * Audit Type * Audit Objective
3	At Level 3 information from lower levels and the following information will be shared: * Audit Report Summary * Do Findings Exist in the Audit Report
4	At Level 4 information from lower levels and the following information will be shared: * Audit Checklist Columns (Type, System, Processes, Deliverables) * Audit Report Columns (Findings, Class) Only finding rows where Proprietary = No
5	At Level 5 information from lower levels and the following information will be shared: * Audit Report Columns (Comment) Only finding rows where Proprietary = No


# Confidentiality Concerns



Confidentiality concerns can also be addressed by segmenting data into individual activities that do not compromise the auditee or the auditor and by anonymising it

Type of Audit Examples	Example Audit Process						
	Request	Approval	Schedule Planning	Auditor Selection	Prepare	Conduct	Report
Clinical Trial Centre	Green	Green	Green	Green	Yellow	Yellow	Red
Affiliates & Marketing	Green	Green	Green	Green	Yellow	Yellow	Red
Laboratory	Green	Green	Green	Green	Yellow	Yellow	Red
CRO	Green	Green	Green	Green	Yellow	Yellow	Red
Pharmacovigilance	Green	Green	Green	Green	Yellow	Yellow	Red
Due Dilligence	Red	Red	Red	Red	Red	Red	Red
Mock Inspections	Green	Green	Green	Green	Yellow	Yellow	Red
Investigations	Red	Red	Red	Red	Red	Red	Red
Pre-Inspection Visits	Green	Green	Green	Green	Grey	Yellow	Grey
CTC Compliance (CRO)	Green	Green	Green	Green	Yellow	Yellow	Red
Other	Green	Green	Green	Green	Yellow	Yellow	Red

 Confidentiality according to preference

 Confidentiality agreement required

 Confidential

# Why would an organisation participate?



Organisations will actively share information if there are tangible benefits that overcome reservations about confidentiality or company-specific methods

- All participants can actively benefit from
  - Shared information that provides new perspective on internal data
  - Access to a pool of standardised and ‘credentialised’ service provider and audit data
  - Analysis of trends, quality heat maps and warning flags for outliers
  
- This prototype is focused on GCP QA although the same principles apply for
  - Reports from monitoring visits or inspections
  - Pre-inspection visits and other quality data collection processes
  - Any other data source (e.g., QRM, ADAMON, study quality assessment data)
  
- Smaller organisations can manage their audit process
  - Without paying substantial license fees for COTS software
  - Can benefit from the larger scale of audit activity and share audit packages
  - Can improve the transparency and robustness of their processes



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