interfacing.

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Empower organizations to efficiently d transform, govern business complexity and continuously improve through process based quality, performance and compliance solutions.

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Quality, GRC, Audit & Continuous Improvement

Interfacing's mission is to empower organizations to efficiently govern business complexity and continuous transformation through process based quality, performance and compliance solutions.

Interfacing's Digital Business Transformation Suite

Business Process Management (BPM)	Quality Management System (QMS)	Governance, Risk, Control, Audit & CAPA (GRC)	Document Management System (DMS)

Automation & Integration (Low Code Rapid App Dev)

Monitoring & Reporting (BI)

Overview

Managing audits without a workflow tool involves storing information in multiple files in a non-centralized information repository.

Our audit management application features a single web-based interface for managing and storing all information relative to an audit.

Some modules are designed for process execution and automation while others are managed independently for administrative use and support.

All modules are interrelated and supplement each other's functions, simplifying the complexity of creating and managing a fully transparent audit cycle.

Relationship Map Between Modules

Data from one module can easily flow and integrate into the other.

Offering highly flexible functionality, all modules, forms and fields are fully configurable.

Terminology may be adapted to support specific business requirements.
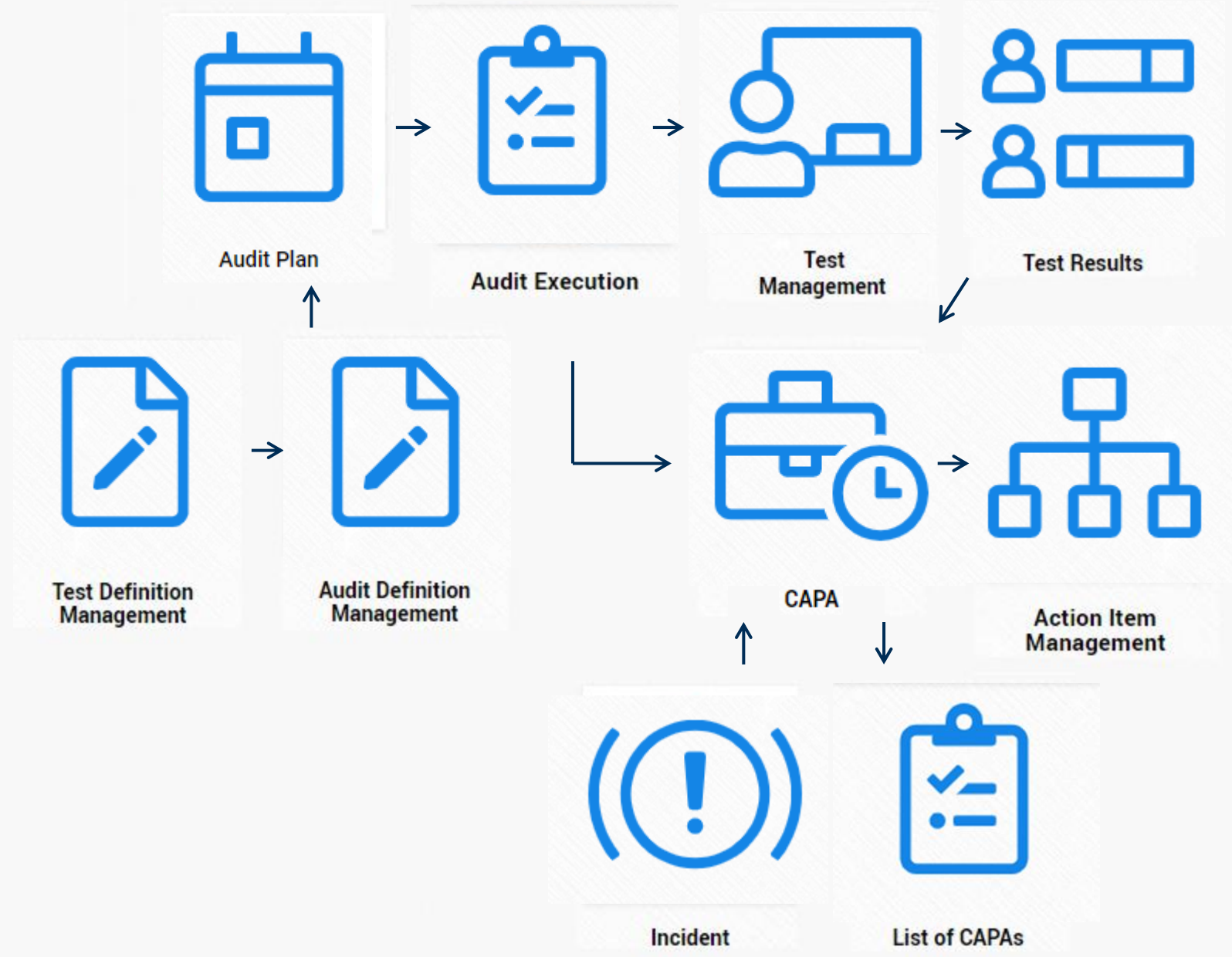
Key Feature Overview by Module

Test Definition Management

Define, map, test, and report on controls and compliance requirements from one module

Audit Plan

Plan the nature, timing and extent of tests, controls, and procedures

Associate tests to audit(s)

List of CAPAs

View the progress of all your current and historical CAPAs in real-time

Run reports on any overdue or pending corrective actions

Track versions and revisions

Audit Execution

Manage internal and external audits status and documentation in a single repository

Test Results

Test repository to view all tests whether in progress or complete

Consult existing results for comparison and evaluation

CAPA

Centralized action item completion monitoring; escalation triggers

Store action item evidence

Integrated to audit & incident management root cause analysis

Incident Management

Real-time incident reporting, tracking, and analysis

Supports multiple geographic locations

Enables follow-up and root cause analysis - escalation to CAPA

Action Item Management

Assign and manage action items through to closure

Communicate action item details via automated/scheduled email notifications

Escalations with real-time status/closure tracking

Audit Definition Management

Enable scheduling of audits, identify issues, generate action plans and assign responsibility

Cross-Application Features

Reusability

Test definition
Audit definition
Standardized audit template

Search

Full-text search available on all fields
Filter and sort all fields for easy retrieval
(e.g., A-Z, Z-A, 1-10, etc.)

Tracking and History

Reporting on all fields of process history
Pass vs. fail audit results
Tracking numbers
Audit trail

Test ID	Test Name	Sample size
	access	

Auditor	Auditee	

Filter   Clear Filter

Test Definitions

		TestNo	Test Id	Test Name	Sample Size	Auditors
1	🗑	7	543-71M-732	Facility access rights	1	Finance Auditor,
2	🗑	12	911-100-001	Access Control Authentication	2	IT Manager ,
3	🗑	16	531-41M-271	Access rights to laboratory	1	

Test Definitions

	Test Id	Test Name	Sample Size
1	821-90Q-32	Pest control	
2	432-91B-29	System authentication proced...	5
3	543-71M-732	Facility access rights	10
4	342-79Z-123	Rhizobium Tests	20
5	745-34C-27	Nodulation Assessment	1
6	641-98V-69	Fusarium head blight	100
7	531-34W94	Reporting Compliance	50
8	911-100-001	Access Control Authentication	3
9	531-41M-271	Access rights to laboratory	12
10	554-66C-390	Data Integrity	40

Tracking

Tracking code : 1147669   Tracking   History

- Process level: **Approved**

Process History

Status	Event	User	Job Position	Job title	Responsible	Task start date	Task finish date
◢ Submit		admin	...				
Test Start Rout		admin	Audit Coordinator				
◢ Wait To Start Audit Plan		admin	...				
◢ Schedule Audit	Auto	admin	...	Schedule Audit	Audit Coordinator	08/01/2019 13:26	08/01/2019 13:40
Approve/Update Test Schedule	Send for Approval	admin	Audit Coordinator	Approve/Update Test Schedule	Process owner	08/01/2019 13:40	08/01/2019 13:41
◢ Approve/Update Test Schedule	Send for Approval	admin	Audit Coordinator	Approve/Update Test Schedule	Audit Coordinator	08/01/2019 13:40	08/01/2019 13:41
◢ Wait for audit executiom	Approved	admin	Audit Coordinator				
◢ Test Execution	Conduct Test SubPrc	admin	Audit Coordinator				
Audit Review	Send to review	admin	Process owner	Audit Review	Anonymous	08/01/2019 13:47	08/01/2019 13:48
◢ Audit Review	Send to review	admin	Process owner	Audit Review	Audit Coordinator	08/01/2019 13:47	08/01/2019 13:48
◢ CheckForCapa	Submit	admin	Audit Coordinator				
◢ Capa SubProcess	Send To CAPA	admin	Audit Coordinator				
Close Audit	Finished Capa	admin	Audit Coordinator	Close Audit,	Audit Coordinator	08/01/2019 13:48	...

Notifications

Schedule periodic/recurring tasks
Assign task notifications based on user or role
Trigger escalations based on pending or overdue tasks
Email or SMS alerts
Complete mobile functionality

Reviews & approval cycles

Automate and accelerate approval cycles
Multiple rounds of reviews to ensure efficiency
Electronic signatures
Evidence of audit supervisory review
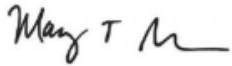
Request | **Approval**

Approval Status

⭕ Approved   🔘 Rejected

Rejection reason
Out of scope

Date

Integration

Integrate data from EPC using REST APIs
Integrate with 3rd party systems

LIST   GRAPH   DETAILS

★ Name ▲

🖥 ☆ COBIT - Control objectives
🖥 ☆ EDC
🖥 ☆ Environment Health and Safety C...
🖥 ☆ Financial
🖥 ☆ Financial Controls
🖥 ☆ ISO 27001
🖥 ☆ ISO/IEC 20000-1
🖥 ☆ ITIL metrics - KPI

Initiation

Tracking Code

EPC Module   EPC Object

Select...   Select...

Dashboards

Quickly generated based off real-time data
Monitor the progress of audits or tests in real-time
Embed charts and dashboards into forms
Drill down into open and outstanding tasks

Reports

Export collected data with a single click
Detailed, automatically generated reports in multiple formats such as Excel, PDF, etc.
Generate detailed reports using COGNOS
Customize reports with your logo

Audit and Test Definition

- Repositories for all audit and test instances

- Narrow your search - select one or many fields for audit or test look-up

- Search and sort through each column (Audit/Test ID, Audit/Test Name, Frequency, Sample Size, etc.) or filter your search by Auditor

- Set security at all levels by role or user

- Connect an audit plan to an object within EPC (e.g., a process, control, etc.)

Audit Process

Audits are triggered-to-start ad hoc or based off a pre-set schedule.

Schedules are set. Changes are verified and result in a final schedule.

On the audit date, tests are executed and results are captured. CAPA may be triggered.

Audit closes depending on the status of a CAPA and final results.

Audit Scheduling
Features & Attributes

Key Attributes

- Auditor and auditee assignment
- Audit deadline
- Trigger to start on
- Prerequisites
- Add multiple tests

Key Features

- Automated audit start date x days before scheduled date
- Automated reminders
- Schedule approval cycle
- Tracking notifications for audit manager
- Auditors/auditees may be hardcoded or managed independently through external module
- Capture all information; export to Word, PDF, or print

Add Test
Features & Attributes

Key Attributes
- Procedure
- Prerequisites
- Auditor / auditee assignment
- Scheduled date and due date
- Sample results

Key Features
- Add and evaluate test samples
- Detail pre-audit preparation work
- Reuse previously defined test form as template and re-assign values or roles easily
- Lock fields by role
- Set validations

Test Execution
Features & Attributes

Key Attributes
- Procedure
- Scheduled date and due date
- Frequency
- Sample size
- Sample results

Key Features
- Establish responsibility by role
- View/edit/add sample results
- Yes/no and/or pass/fail radio buttons determine sample effectiveness
- Upload multiple attachments to test samples; can be downloaded at any future step
- Notifications sent to audit manager
- Conversation threading; comment textbox facilitates collaboration between users

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Execute Test and Capture Test Results

Test Name

Fusarium head blight

Procedure

Grain Commission plate test:
- Five-day test.
- Gives a percentage of F. graminearum found in each sample to 0.5%.
- Is an excellent follow-up for the fusarium DNA test.

Test Description

Pre-requisites

Sample 1 ton of grain from multiple sources
Organize sample 2 days prior

Scheduled Date	Due Date
17/01/2019	25/01/2019

Frequency	Sample Size
	100

Auditors	Auditees
Quality Analyst	Finance Auditor

Sample Results

		Sample Title	Auditee	SampleNo	Reference Id	Effectiveness	Accurate	PassFail
1	🗑	001-FUSHB-19	Finance Auditor	3	1	☑	☑	☑
2	🗑	002-FUSB-19	Finance Auditor	3	1	☐	☑	☐

+ Add   ✎ Edit   View   📄 Export to excel

|◄ ◄ ▶ ►| 20 ▼   1 - 2 of 2 items ↻

Effectiveness		Accurate		Pass/Fail	
○ Yes	● No	● Yes	○ No	○ Pass	● Fail

Comment

Retest the second sample

Apply

Test Sample
Features & Attributes

Key Attributes
- Test schedule information
- Assign role to test
- Sample number
- Capture effectiveness, accuracy and pass or fail

Key Features
- Establish responsibility by role
- Add multiple samples without exiting the 'Add Sample' window
- Mandatory fields to ensure accuracy
- Validations on fields that trigger pass or fail results
- Field to upload multiple attachments
- Export sample record to Word, PDF, or print from form

Audit Review Form
Features & Attributes

Key Attributes
- All audit information inherited and static
- Overall audit result (pass/fail)
- Send to CAPA (yes/no)

Key Features
- Dropdown to grade audit overall pass or fail
- Dropdown to trigger automatic escalation to CAPA
- Validation set to determine roles responsible for escalation
- Audit Review form easily reassigned if higher authority level sign-off is required
- View all process history preceding the form; who was responsible, task start date, task end date, etc.
- Export all captured information to Word or PDF, or print form

Audit Report

Audit Name	Description	Subject	Prerequisites	Auditors	Days To Alarm	Frequency	Type	Location
Asset Control	Verify status and condition of assets.	ISMS	- Asset list	Auditor 1,	10	Annually	Internal	Warehouse
BPCA	This audit relates to the IS of the Steel Foundry	ISMS	- Documents - Employees	Analyst,	20	Annually	External	Steel Foundry
Event ID 4625	This description contains all you need to know about rhizobium tests	Finance	Sample tests	Auditee 1,	10	Annually	External	Location 1
Financial compliance	Improve financial documentation; check internal policies; review accounting system	Strategic Planning	Previous financial records and accounting ledgers dating back to 2016	Analyst,		Annually	Internal	Corporate Office
Internal Process Audit	This is a standard test for basic compliance of the processes with the systems.	Procure to Pay process audit	1. Determine audit period 2. Identify Processes to be audited 3. Identify related systems 4. Identify Auditees and Process Owners 5. Collect relevant process documentation, SOPs, process map etc. 6. Check for access to related systems. If no access, request for access 7. Schedule Audit 8. Prepare Audit Checklist	Auditor 1,	15	Quarterly	Internal	Steel Foundry

Drilldown from the top-level report to the specified drilldown report visualizations (shown next).

View all calculated metrics and data related to an audit instance, such as:
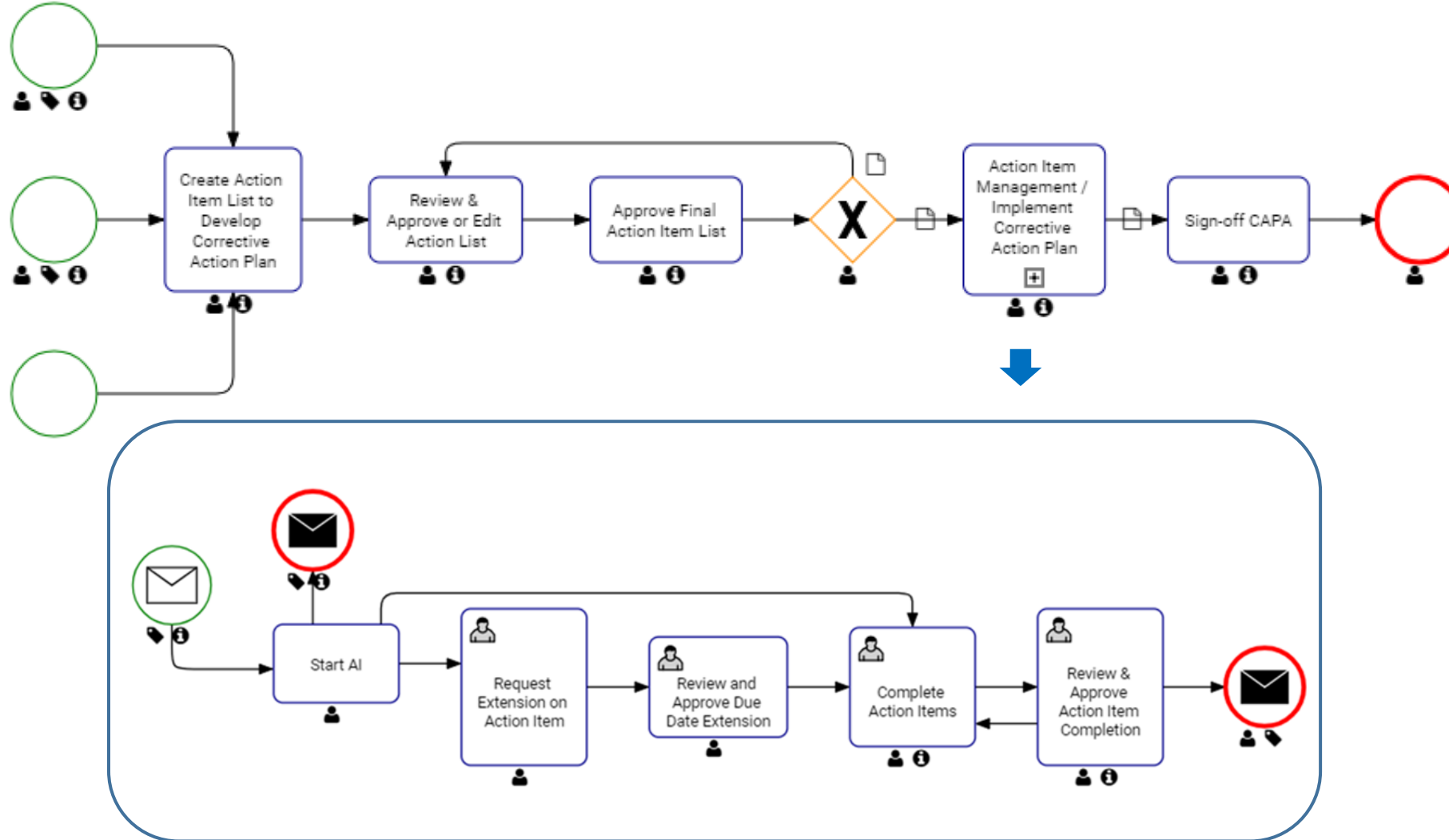- the status of each associated test
- the adequacy and effectiveness of each test

CAPA Process

Trigger CAPAs via failed audits, incidents, or ad hoc requests

Assign actions to specific resources with deadlines

Manage action item extension request (incl. single request limit)

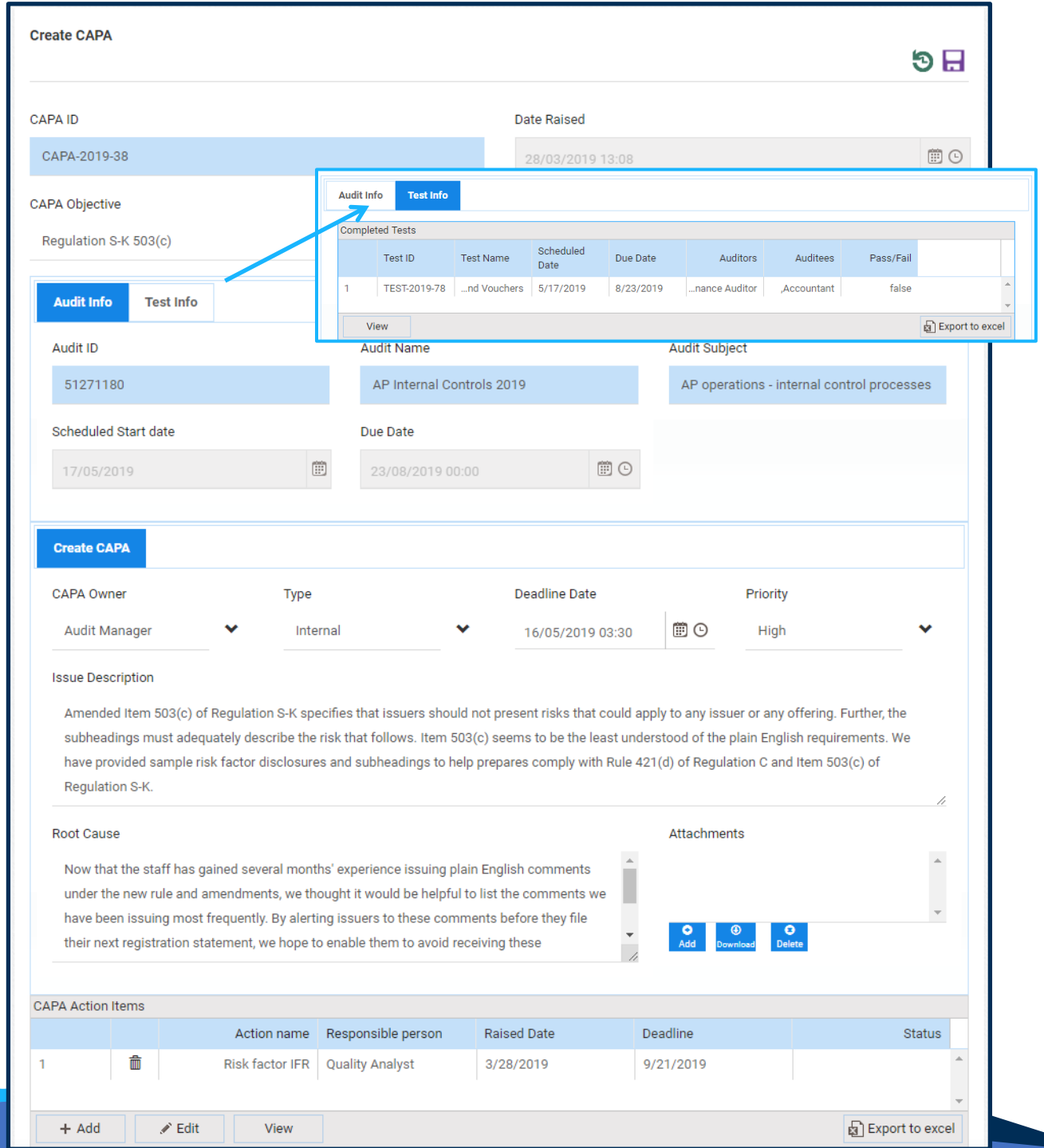Collect & store action item evidence on completion

Create Action Item List to Develop Corrective Action Plan

Review & Approve or Edit Action List

Approve Final Action Item List

Action Item Management / Implement Corrective Action Plan

Sign-off CAPA

Start AI

Request Extension on Action Item

Review and Approve Due Date Extension

Complete Action Items

Review & Approve Action Item Completion

Create CAPA
Features & Attributes

Key Attributes

- Date raised
- Type
- Deadline date
- Issue description
- Root cause
- CAPA action items
- Test Info tab – displays all completed tests inherited from previous form

Key Features

- Failed audit or incident information inherited on form
- View/edit/add multiple CAPA action items
- Responsible roles and status of action items available in real-time

Add CAPA Action Item
Features & Attributes

Key Attributes
- Action item owner
- Action type
- Deadline
- Status
- Remaining days until start

Key Features
- Status dropdown:
  describe state of action item (e.g., addressed, not addressed, requires extension)
- User interaction within comment field
- Create multiple action items in sequence without exiting form
- Escalation triggers set based on deadline
- Collaboration / communication thread between users
- Supports multiple attachments

Add Capa Action Item

Action ID	Action Item Name
001-REG	Risk factor IFR

Action Item Owner	Action type	Priority
Quality Analyst	CAPA	High

Raised Date	Deadline	Remaining Days Until Start
28/03/2019	21/09/2019	

Evidence

To illustrate the value of risk factors disclosures, let's assume that, just after an IPO, an Emerging Growth Company identified a significant deficiency in internal controls. EGCs are exempt from ICFR reporting requirements. Moreover, significant deficiencies that do not rise to the level of material weakness are not normally disclosed in ICFR reports. We would think that this information should be important to investors, but with no ICFR report, would any disclosure be available? In some cases, disclosure controls may provide some insight. In other cases, the risk factors section may be the only option.

Description

In connection with our December 31, 2015 and 2014 audits, we identified a material weakness in our internal control over financial reporting. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements

Attachment

Scope Sheet.doc
Template_JD.doc
Audit_AR_ENG.doc

Add   Download   Delete

Comment

Create first draft copy of sample report for revision by May 23 2019.

Apply

Save and Return   Save and New

Action Item Form
Features & Attributes

Key Attributes
- Action item name
- Action item owner
- Action type
- Deadline
- Status

Key Features
- Notification sent to manager once Action Item Owner opens Action Item form
- Status dropdown: indicates if AI is invalid, closed, in progress, or if an extension was requested
- Process owner reviews & approves
- Electronic signatures

Review and Approve AI Completion

Action ID
12741183

Action Item Name
Risk Factor IFR

Action Item Owner
Quality Analyst

Action type
CAPA

Priority
High

Raised Date
28/03/2019

Deadline
26/04/2019

Remaining Days Until Start
29

Evidence
At the same time, the overwhelming majority of companies with a current material weakness had a parallel risk factor disclosure. Only 18% did not disclose such a risk factor, and we are not sure why. If anything, a current, actual material weakness emphasizes that the risk is no longer merely hypothetical.

Description
The material weakness pertains to the breadth of our internal accounting team. Specifically, we do not have a sufficient number of accounting personnel to effectively design and operate proper internal controls over financial reporting. We are working to remediate the material weakness. We have begun taking steps and plan to take additional measures to remediate the underlying causes

Attachment
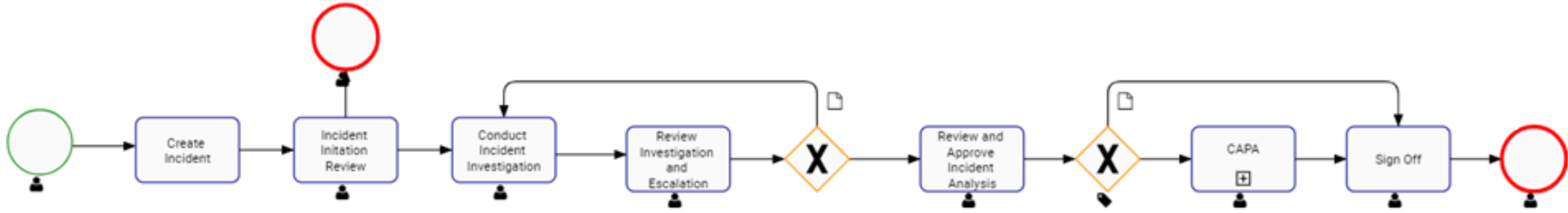Template_JD.doc
Scope Sheet.doc

Add   Download   Delete

Status
In Progress

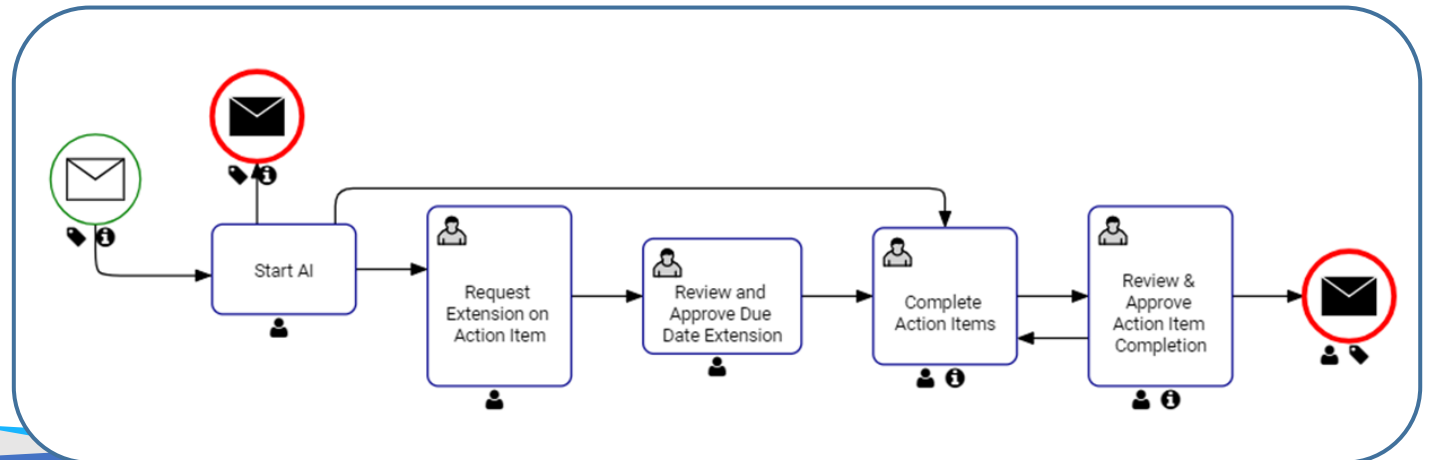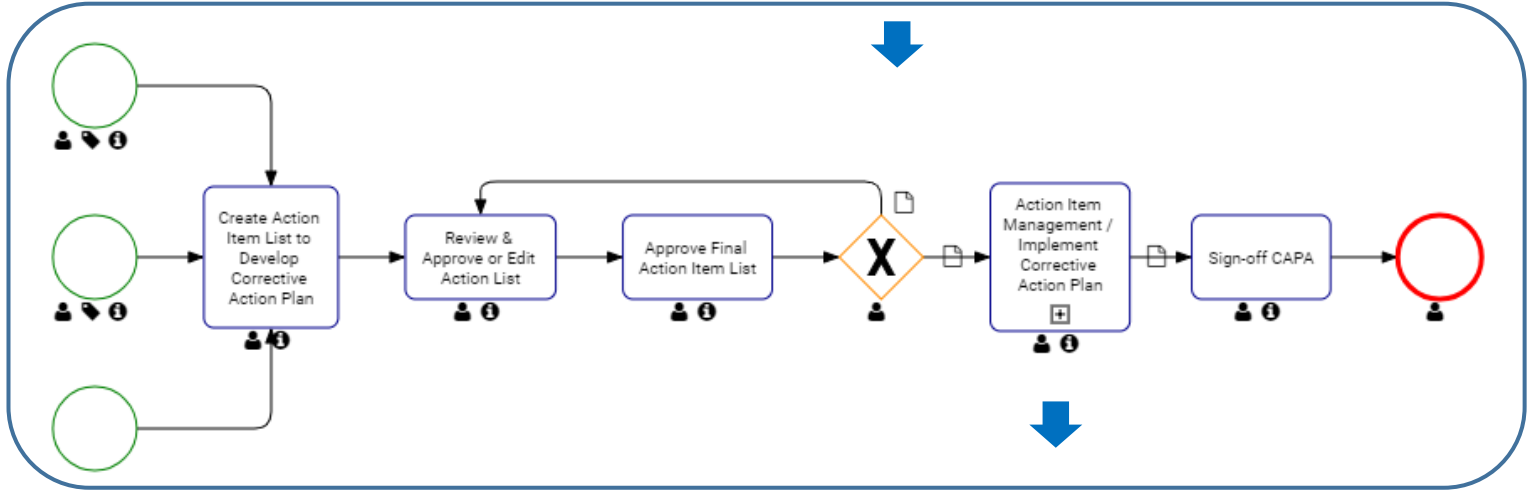**Comment**

Incident Management

Create incident ad hoc; if accepted after first review, incident process closes

Quality Assurance Agent triggered to conduct incident investigation; root cause and risk analysis

Multiple review and approval cycles to ensure accuracy and compliance

Failed analysis results trigger CAPA process

Incident Form
Features & Attributes

Key Attributes
- Tracking code
- Incident location
- EPC object
- Data source
- Date of occurrence and date found
- Observation
- Requirement

Key Features
- Incident graphs and reports generate from data; export to Word, PDF, or print
- Connect an incident to an EPC module, object or incident
- Data source text field captures additional specificity
- Upon submit, follow up on incident request at any step in the process by tracking code

Incident Investigation
Features & Attributes

Key Attributes
- Risk analysis
- Root cause analysis
- Assign responsibility by role or user
- Date

Key Features
- Information from previous Incident Initiation form inherited as a tab for reference
- Trigger escalation to CAPA from tab (shown right) – if CAPA is needed, description field to enter in reason
- Electronic signature

Conduct Incident investigation

| Initiation | **Investigation** | Escalation to CAPA |

Risk Analysis

Make sure to regularly check your cords and appliances in the kitchen. If you notice a cord is starting to fray or break, then it's time to replace the appliance.

Description

In general, you should replace your appliances every 10 years or less. Just by replacing the old appliances in your kitchen, you can save your office from a fire or another hazardous situation.

Root Cause Analysis

Left food unattended while cooking; caught on fire.

Date

28/03/

Comment

| Initiation | Investigation | **Escalation to CAPA** |

Need Escalation to CAPA?   Description

● Yes   ○ No   Uncover all possible hazards in the kitchenette.

Comment

Review Investigation
Features & Attributes

Key Attributes
- All fields inherited from Incident form
- Accountability assigned by roles and users
- Date of signatures

Key Features
- Electronic signatures attached to user profiles
- Triggered process-loop back if form is rejected
- Validation on fields to ensure form may not be submitted without signature, etc.
- Multiple approval cycles may precede any step

Review Investigation and Escalation

| Initiation | **Investigation** | Escalation to CAPA |

Risk Analysis

Make sure to regularly check your cords and appliances in the kitchen. If you notice a cord is starting to fray or break, then it's time to replace the appliance.

Description

In general, you should replace your appliances every 10 years or less. Just by replacing the old appliances in your kitchen, you can save your office from a fire or another hazardous situation.

Root Cause Analysis

Left food unattended while cooking; caught on fire.

Incident Owner		Date		Quality Assurance Manager		Date	
Joe Clark		28/03/2019 14:23		Benjamin Franklin		28/03/2019 14:23	

Incident Report

| Incident Name	Issue Name	Issue Description	Root Cause	Due Date	Description
Product 405	Product Recall n.11	21 CRF 2.143.221 test failure	Repeated test failures of product not investigated due to negligence.	Apr 25, 2018	Inadequate investigation of failed particulate inspection. Failure to document action regarding instrument calibration check which did not meet specification.
Compliance s.404	Failure to comply with SOX Section 302.2	The current system does not track all user logins access to all computers that contain sensitive data and detects break-in attempts to computers, databases, fixed and removable storage, and websites.	Not all modules were obtained from vendor	Apr 23, 2018	Acquire the Security Access Management Module in the ERP system Train super users Design permission maps Integrate with AD Implement and retrain users
TRK	TRK# 9357	TRK# 9357 was implemented to address execution of varied manual interventions performed during aseptic filling operations. Inspection found that the laboratory manager had documented "NIL" (i.e., no growth for this plate), while the same laboratory manager comfirmed microbial growth in the presence of the investigators. Later during the inspection, the FDA investigator asked to see the original plate and was told that it had been destroyed.	The laboratory manager misread the plate count, and this deficiency was the result of a human error.	Apr 24, 2018	Extend corrective actions to include component suppliers, training, acceptance activities and field actions.
Xantha v2	Biopharmaceutical xantha v2 does not conform to health & safety regulation 14.2	The forms utilized don't follow the flow of the procedure; the forms do not provide enough space for more than a brief entry; verbal decisions are not written down; responsible people are assigned but timelines for the follow-ups are not given and are vague.	Nonconformities are not adequately categorized and trended - root causes of existing nonconformities are not adequately investigated or addressed to eliminate the reoccurence of the nonconformity discrepancy	Apr 23, 2018	Revise all Quality Assurance Procefures to emphasize CAPA and to link discrepancy reporting and disposition to preventive acion. Initiate a trending and root cause analysis program; present those programs to management and to staff. Provide a Quality update at the monthly staff meeting.
Login Requests	Noncompliance with s.404 (a)	System must track all login requests.	Omitted requirement in RFP.	Apr 23, 2018	Purchase component - map permission maps - implement maps - train users

Drilldown to view subsets of each Incident Report to expose and consult all related CAPA and Action Item details.

	List															
Action Priority	ActionType	Submission Date	First Name	Last Name	Email	Comments Scheduling	Justification	Incident Name	Incident Location	Priority	Incident Prerequisites	Incident Procedure	Sample Size	Steps Taken	Attachments	Action Name
Low	Corrective	April 26, 2018	Erin	Haurylchyk	EHAURYLCHYK@INTERFACING.COM	Comments	Justification	TRK	Maintenance Office	Low	1. All AM Procedure documents available 2. Process owner must be available for 2 hours for interviews	1. Review AM documents 2. Inspect for accuracy and completeness (ISO document control) 3. Interview process owner on control methods	5 AM documents chosen at random		NA	NA

Reports and Dashboards

Total number of incident requests in different locations
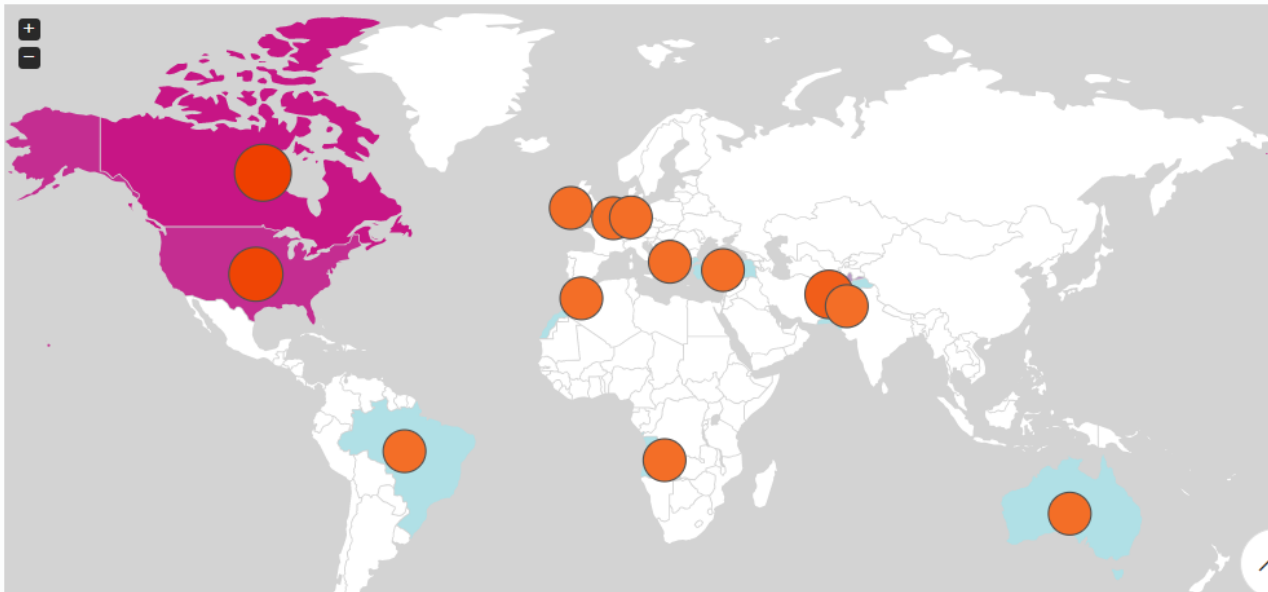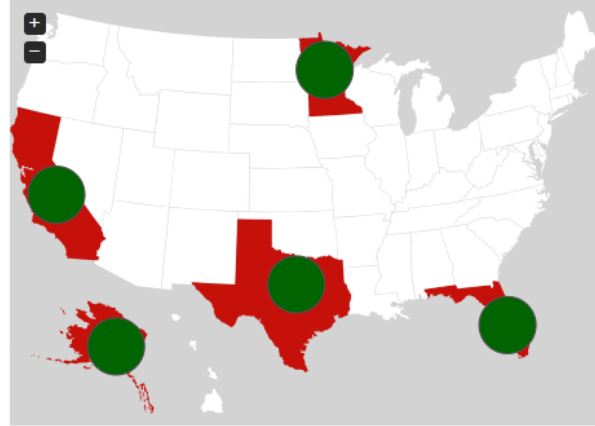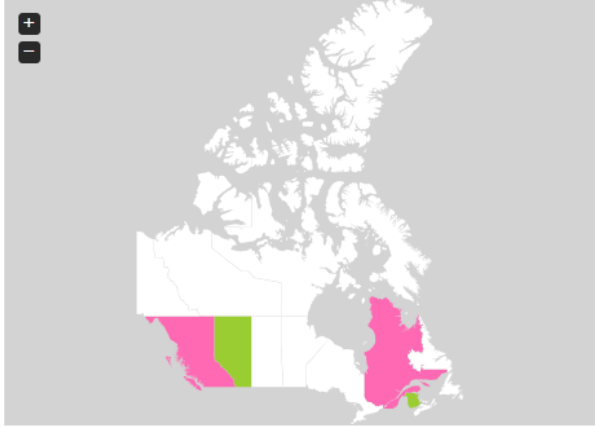
- Incorporate dashboards and charts into forms
- Monitor test progressions, percentage of resolved incidents in real-time
- View number of incidents logged per location, within a specific time frame
- Drill down into metrics