



QIT Consulting, Inc.

QIT Quality Management System

a platform to build a dynamic management system

Program Introduction

Contents



● QIT Consulting and Our Clients

● Existing System at a Glance

● Technology of our Systems

● A Future System for Your Business

● Next Step

QIT Consulting and Our Clients

QIT Consulting, Inc.

- We are a Software Design Company with 20+ years experience in:
 - Quality Software Designs
 - Supplier Management and Outsourcing Software
 - On-site Business Improvement Consulting and Program Training
- WHQ is in Norwalk Connecticut USA *(30 miles north of New York City)*
 - Email: sales@qitconsulting.com
 - Website: [Http://www.QITConsulting.com](http://www.QITConsulting.com)
 - Sales: (203) 663-0528

QIT's Client-base



- ❑ Automotive
- ❑ Manufacturing
- ❑ Aviation Industry
- ❑ Medical Device
- ❑ Service
- ❑ Engineering
- ❑ OEM/ODM
- ❑ IT Service
- ❑ Transportation

- ❑ Chemical
- ❑ Hospital and Clinic
- ❑ Military and Defense
- ❑ Electronic
- ❑ Injection Molding
- ❑ Cosmetic Products
- ❑ Non-profit
- ❑ and many more

Some of Our Clients



GE



Belkin Cop.
Computer Accessories



Citrix
IT



Orion Registrar
ISO Registrar



Means Industries
Auto Parts Supplier



CMC/CLA
Auto Parts Supplier



Probiotec
Bio Tech



Alphawest
IT Service



MillerCoors

Some of our Clients cont'



A Division of Tyco
Medical Devices



MedBen
Health Care



Riley
Medical Devices



Presidential Airways
Aviation



Executive Jet
Aviation



Virgin America
Aviation



FLIR System
Defense



Canberra Fertility Center
Hospital



Vantage Mobility

For more details please visit <http://www.qitconsulting.com/Clients.htm>



QIT Quality Management System

- What is QIT Quality Management System
- Key Benefits
- System Flow

What is QIT Management Information System

- It is a platform that contains 14 standard modules
 - CAPA and SCAR – utilize CAR to track resolutions for issues
 - Complaints – customer complaints management
 - Nonconformance – internal defects and issues
 - Engineering Change ECN/PCN – engineering change or product change from suppliers
 - Audit – internal or external/supplier system audit
 - Document – internal online document control
 - Training – online training management
 - Project Management – for new product development projects/ APQP/PPAP and etc.
 - PO Management – PO Status, Online Rate, Supplier PPM, cost and etc.
 - Inspection – inspections and supplier quality management
 - Gage Management
 - Maintenance Management
- Each module can be used as a standalone program or configured with other modules to create a complete system

Key Benefits

- Comply and go beyond
 - Complying with ISO9000/QS9000, ISO14000 and FDA 21 CFR Part 11
 - A true closed-loop system that equips with built-in problem solving tools, corrective action management tools, root cause analysis tools and action effectiveness review features
- Save time and administrative cost on your everyday tasks
 - Improving productivity by 80%, reducing operating cost by 24% in the first year and 72% thereafter
 - Highly configurable and can be customized to meet the needs of any organization in any industry
- Our software incorporates best practices from other businesses

Next Generation Web-based System

QIT Quality Management Suite

Current User: Administrator (Administrator/Engineering)
Current User Count: 0
Session Timeout: 28:27

Home Dashboard Reports Tools

Choose Your Application

Dashboard

CAPA
Internal corrective action and preventive action management

SCAR
Supplier corrective action and preventive action management

Complaints
Customer complaints management and resolutions tracking

Nonconformance
In-process nonconformance/defect management

Project
Portfolio, Program and Project management

Change Request

Training
Online training management and training record keeping for off-line training

Inspection
Manage Incoming inspection

Reports
Reports

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QIT Quality Management Suite

Current User: Administrator (Administrator/Engineering)
Current User Count: 0
Session Timeout: 29:54

Home Dashboard Reports Tools

CAPA Status Report

Search

Group By: Year

Year	Open	Pending	Verification	Overdue	Closed On-time	Closed Delayed	Total	Avg Days Open
2015	2	1	1	4	5	0	13	2.00
2014	0	0	0	25	2	2	29	1.20
2013	0	0	0	61	2	4	72	7.73
2012	0	0	0	77	5	0	82	10.05
2011	0	0	0	25	4	0	29	0.70
2010	0	0	0	31	1	0	32	499.40
2009	0	0	0	30	0	1	31	52.00
2008	0	0	0	86	13	4	103	-766.67
Total	2	1	1	339	37	11		

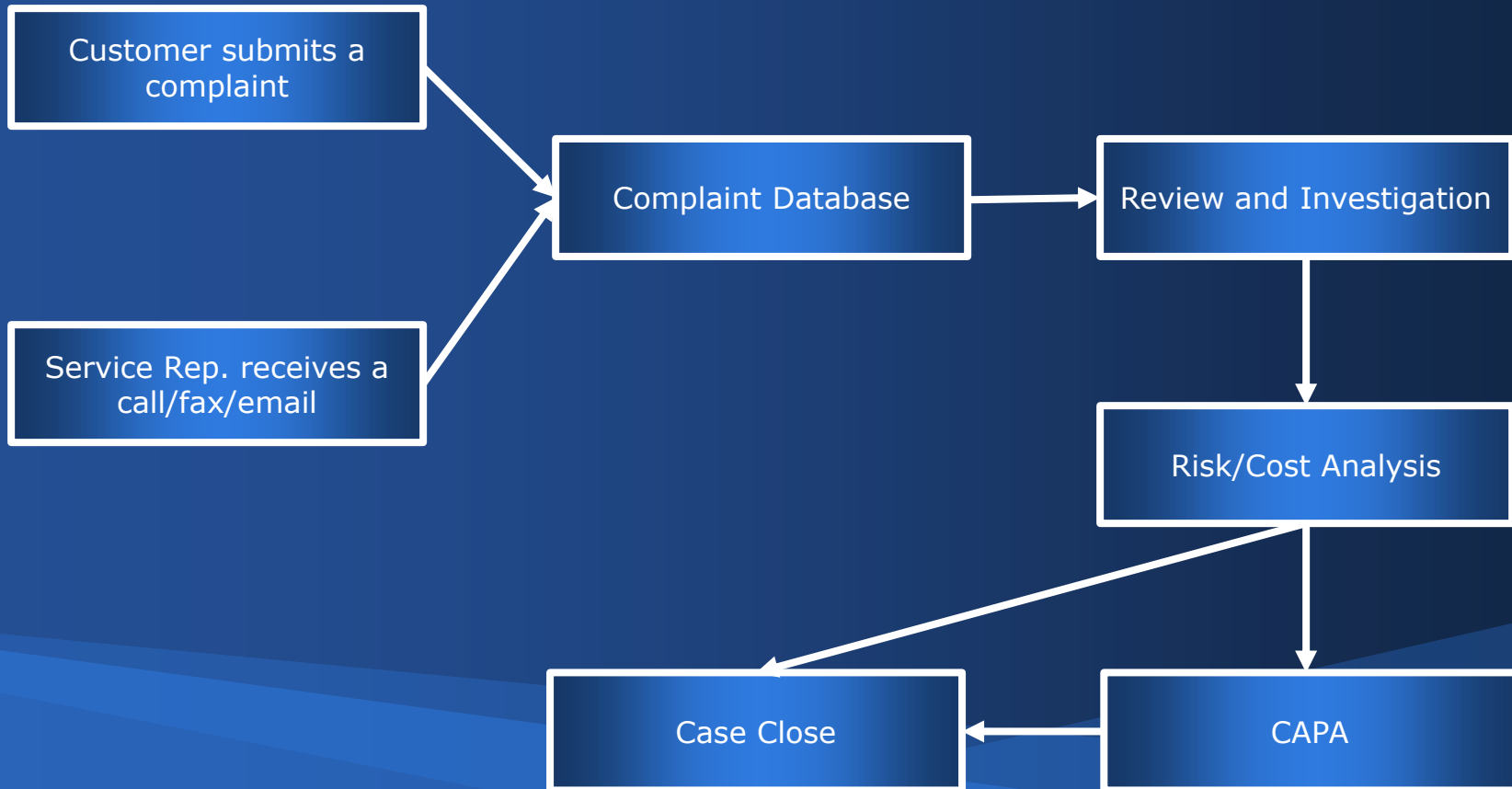
Page: 1 Total Record: 8

Export To Excel Back ALL

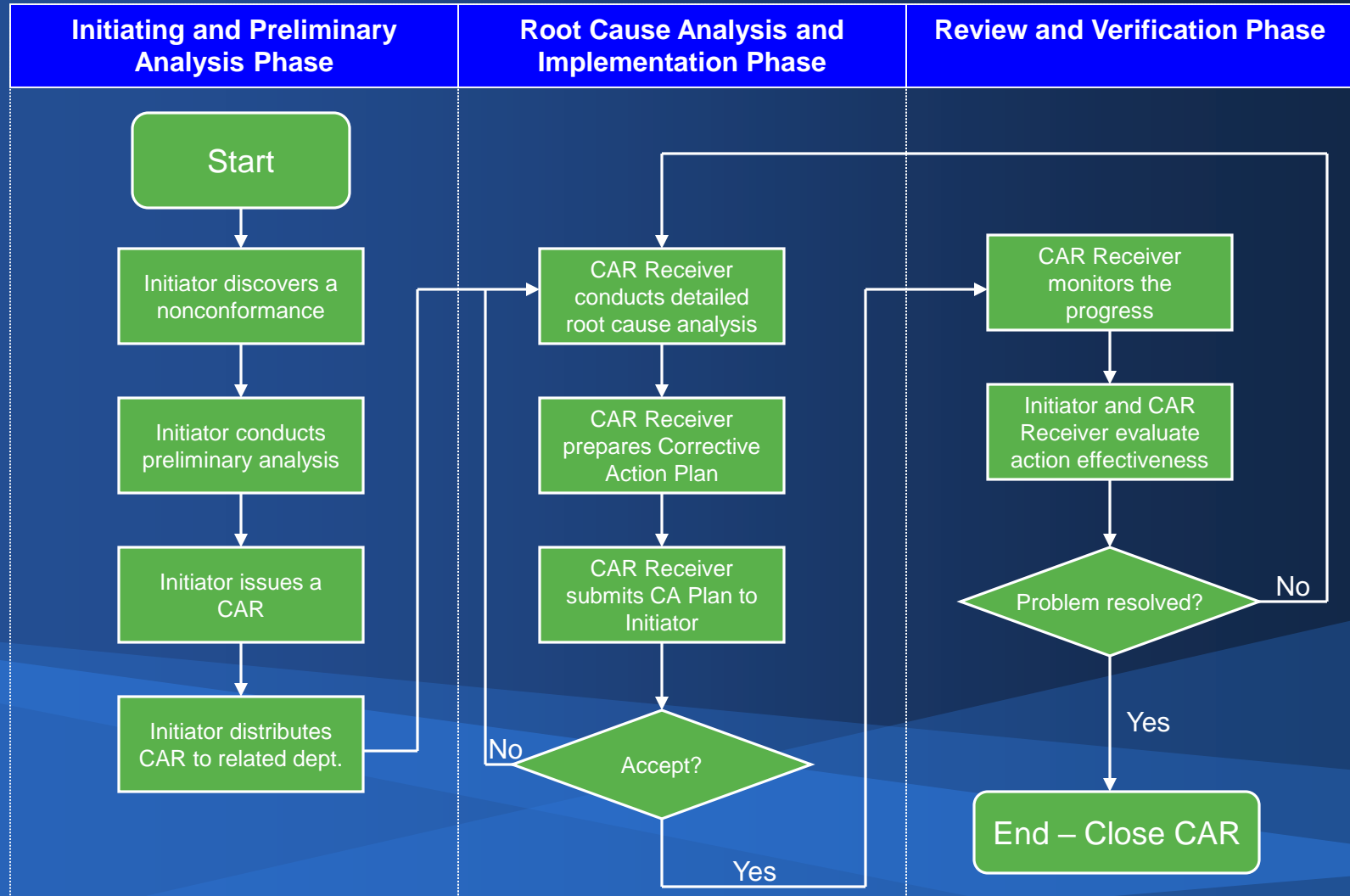
CAPA Status Chart

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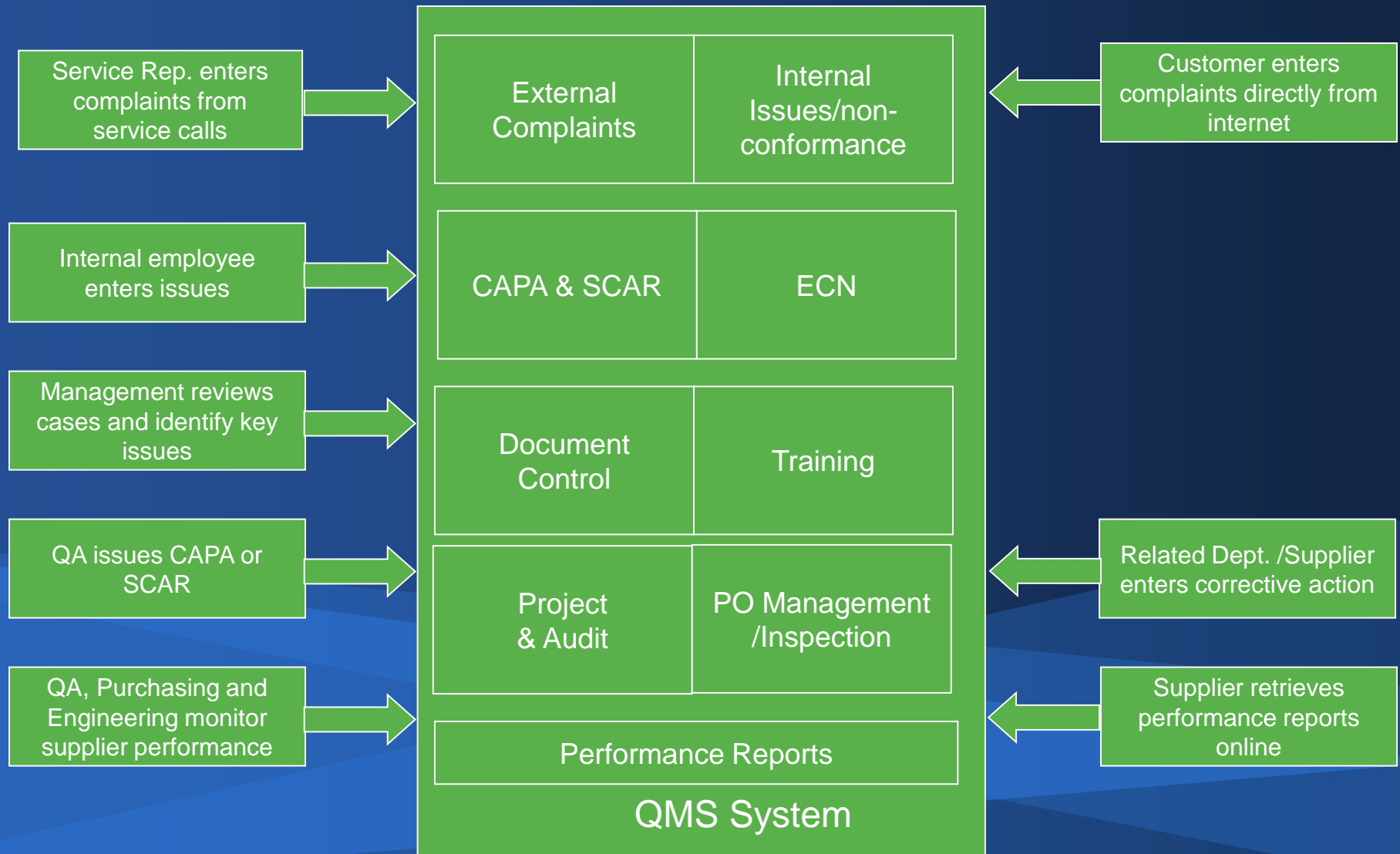
Complaint Mgmt. Process Map



CAR System Introduction - Process



System Flow



Technology of Our System

- Advanced Business Process
 - Next Generation, web-based global QMS, CRM and SCM
 - Real-time data tracking and reporting
- The Latest in Information Technology
 - Microsoft .net C # - flexible and scalable solutions
 - MS SQL Server 2008/2012 - secure and reliable data management
- Windows, iOS, and Android compatible
 - IE8+, Firefox, Google Chrome and Safari
 - Tablets support - iPad, Nexus, Chrome Book and more
- QIT Web Hosting from a SSAE 16 SOC I Certified Data Center
 - 24x7 network monitoring
 - Fiber optic network w/ IP backbone: AT&T, Sprint, Verizon, Cogent
 - Power conditioning, UPS and generator farm
 - Offsite, Vaulted, SAN backup or disaster recovery

A Future System for Your Business

Customization Possibility

- QIT's programs are built on a flexible platform, and it is a framework for our customers to incorporate with new features such as
 - Deviation Request, Investigation, Reject Control and etc.
 - Customer's terminologies and logo
 - Customized high quality reports
 - New fields to capture more information
 - New program functions and new modules that are based on customer's specific requirements
- All customizations could be done in a reasonable cost

Flexible Pricing and Implementation

- QIT offers flexible pricing structure to suite to customers' needs
 - SaaS Per-Concurrent-User Pricing
 - Add all users to the system
 - Customer pays a monthly fee to use the program
 - Opt-out at any time by stopping the payment
 - Lower the upfront investment and minimize the project risk
 - Traditional Buying
 - Customer buys the program upfront and owns the program
 - Customer can host the program at its own server
 - Higher upfront investment
- Starting from small project then evolving to a complete QMS and SCM solution to reduce project risk
 - Normally our customers start from CAPA and SCAR module
 - Once they have more experiences they add PO Management, Project and other modules

Why QIT

- Comply and go beyond
 - Complying with ISO9000/QS9000, ISO14000 and FDA 21 CFR Part 11
 - Built-in root cause analysis tools
- Our software utilizes advanced process improvement and quality assurance tools to help you improve productivity and reduce cost
- Our software incorporates best practices from other businesses
- It simply works! Our software packages have been used by companies e.g. GE, Citrix, Probiotec, Miller Coors, Sonos and Tyco, from Manufacturing, IT, Service, Food and Drug, Electronic, Aviation and other business sectors.
- Cost-effective, Quick Turnaround, Customizable and Scalable



Next Step

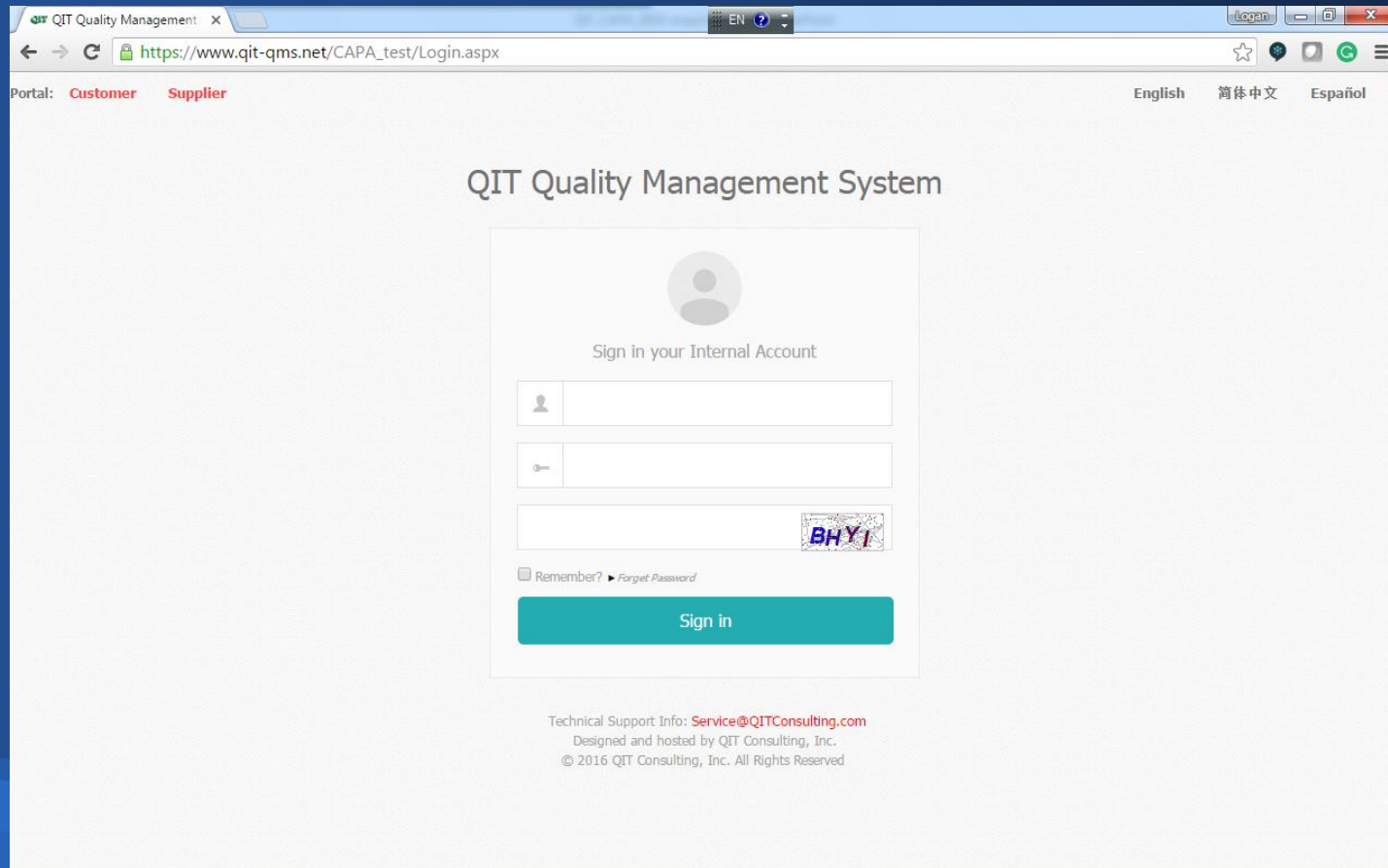
Next Step

- Try the full-function demo at QIT's demo site
- Work together with QIT to finalize your customization requirements, or
- If you wish to purchase an off-the-shelf program, please contact [QIT Sales Team](#) to process your order
 - your program will be set up in as little as 48 hours after your payment has been received

Acronym

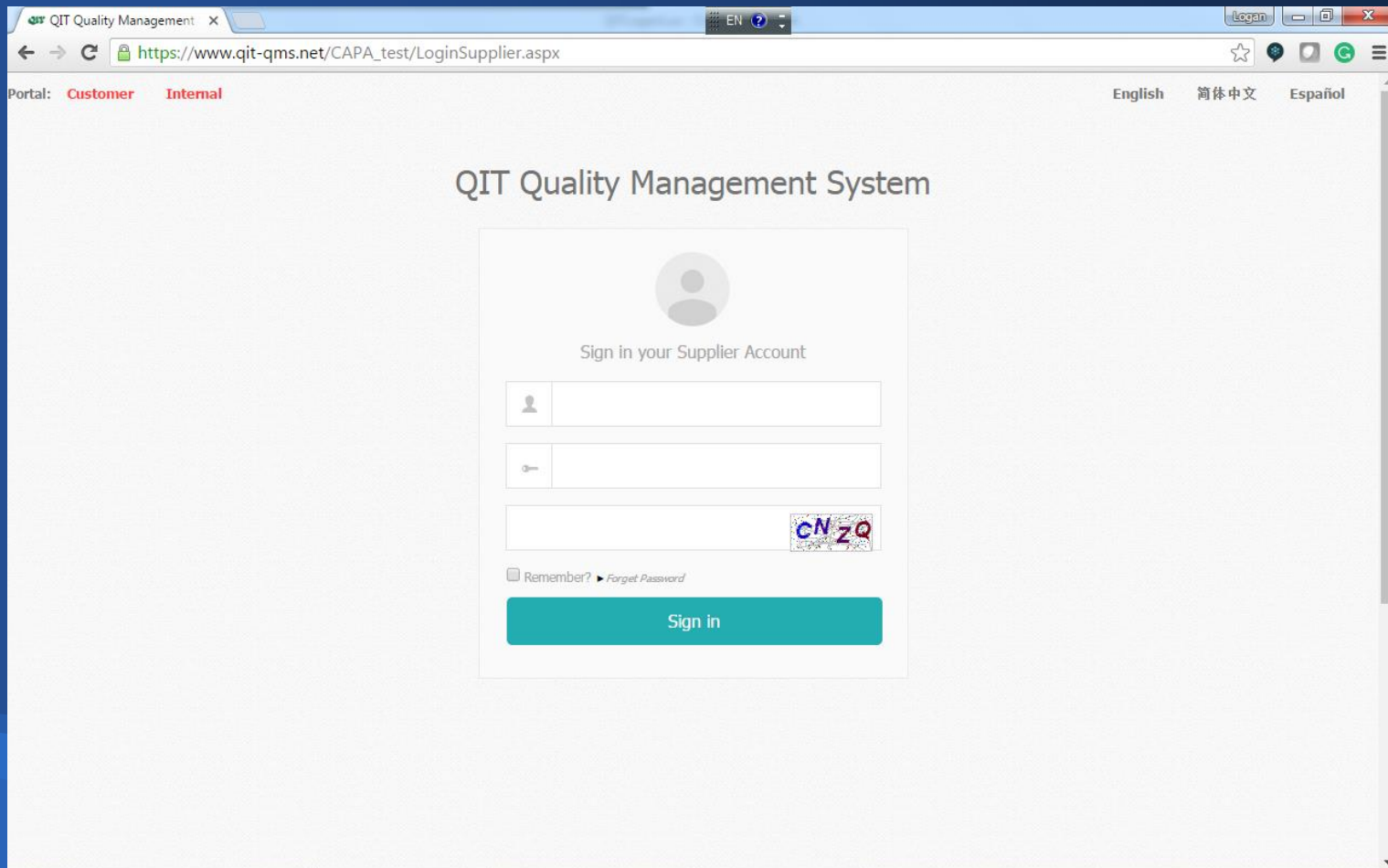
- QMS – Quality Management System
- CRM - Customer Relationship Management
- SCM - Supply Chain Management
- CAPA- Corrective action preventive action
- SCAR – Supplier corrective action request
- CAR- Corrective action request
- APQP – Advanced product quality planning
- PPAP- Production part approval process
- ECN – Engineering change control
- PCN – Product change control
- 4W1H – Who, when, where, why and how
- 4M1E/Fishbone Analysis – Man, machine, method, material and environment
- OEM - Original Equipment Manufacturer
- PPM – Defective Part per million (defective rate)

Customizable Program



- Fully customizable program
- Each customer has its own URL, database and front-end
- Contemporary and simplified outlook
- Validation code to enhance system security
- Self-service password reset function

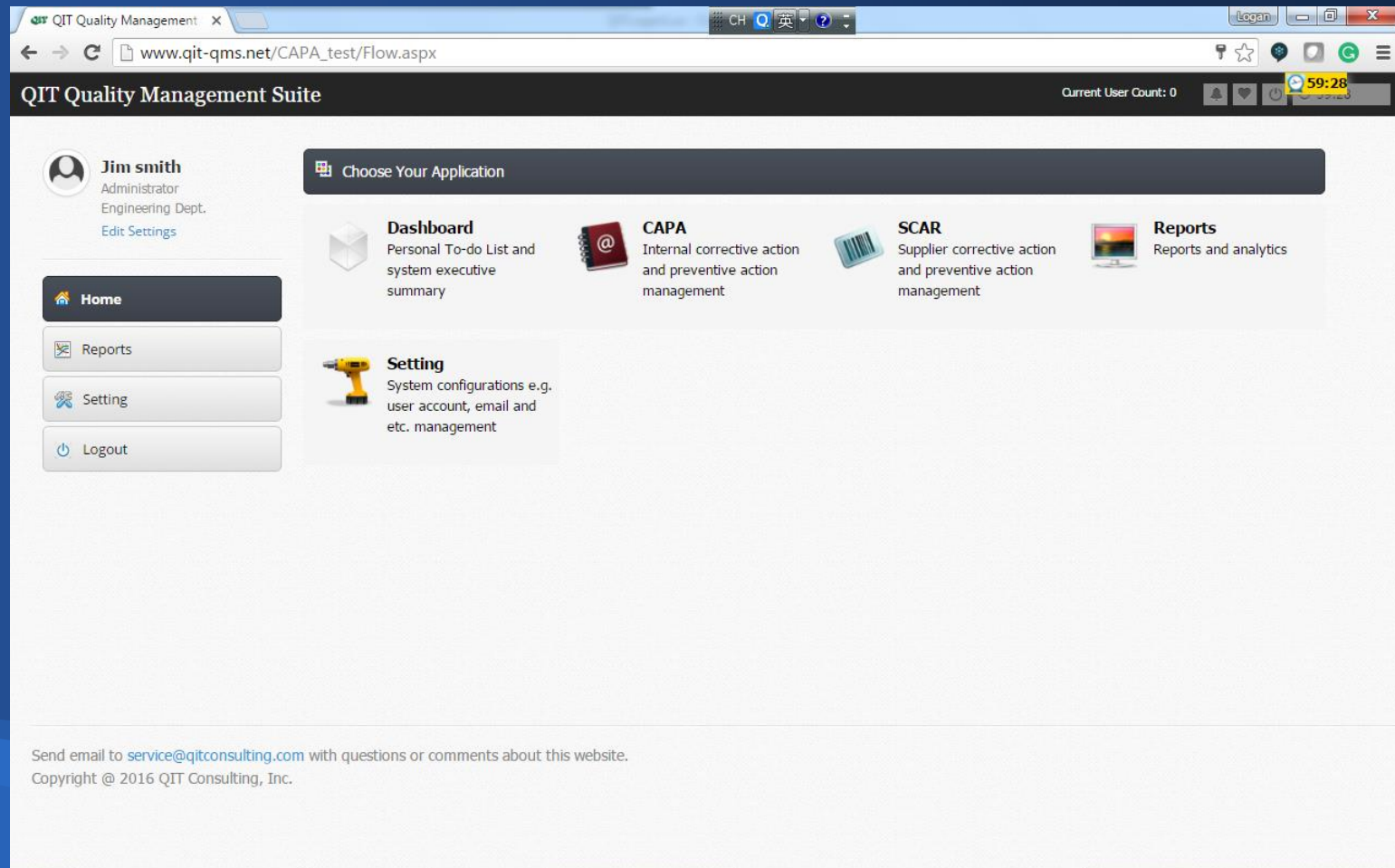
Supplier Login Screen



The screenshot shows a web browser window with the address bar displaying https://www.qit-qms.net/CAPA_test/LoginSupplier.aspx. The page title is "QIT Quality Management System". In the top left corner, there are links for "Portal: Customer" and "Internal". In the top right corner, there are language options: "English", "简体中文", and "Español". The main content area features a login form titled "Sign in your Supplier Account". The form includes a user icon, a password field with a key icon, a CAPTCHA image showing "CN ZQ", a "Remember?" checkbox with a link to "Forgot Password", and a teal "Sign in" button.

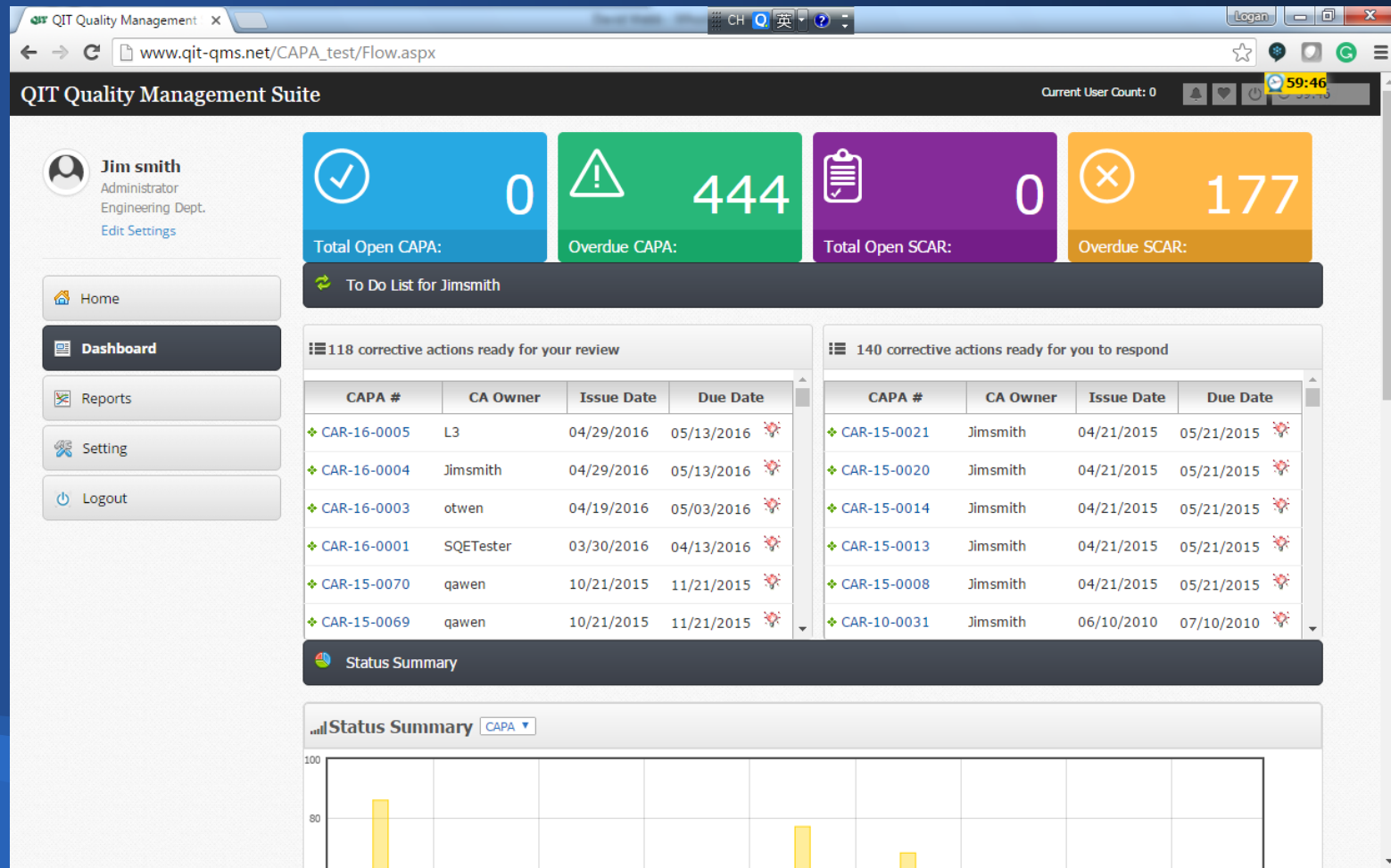
- Separated supplier login screen and access URL for easy program accessing

Easy-to-Navigate Layout



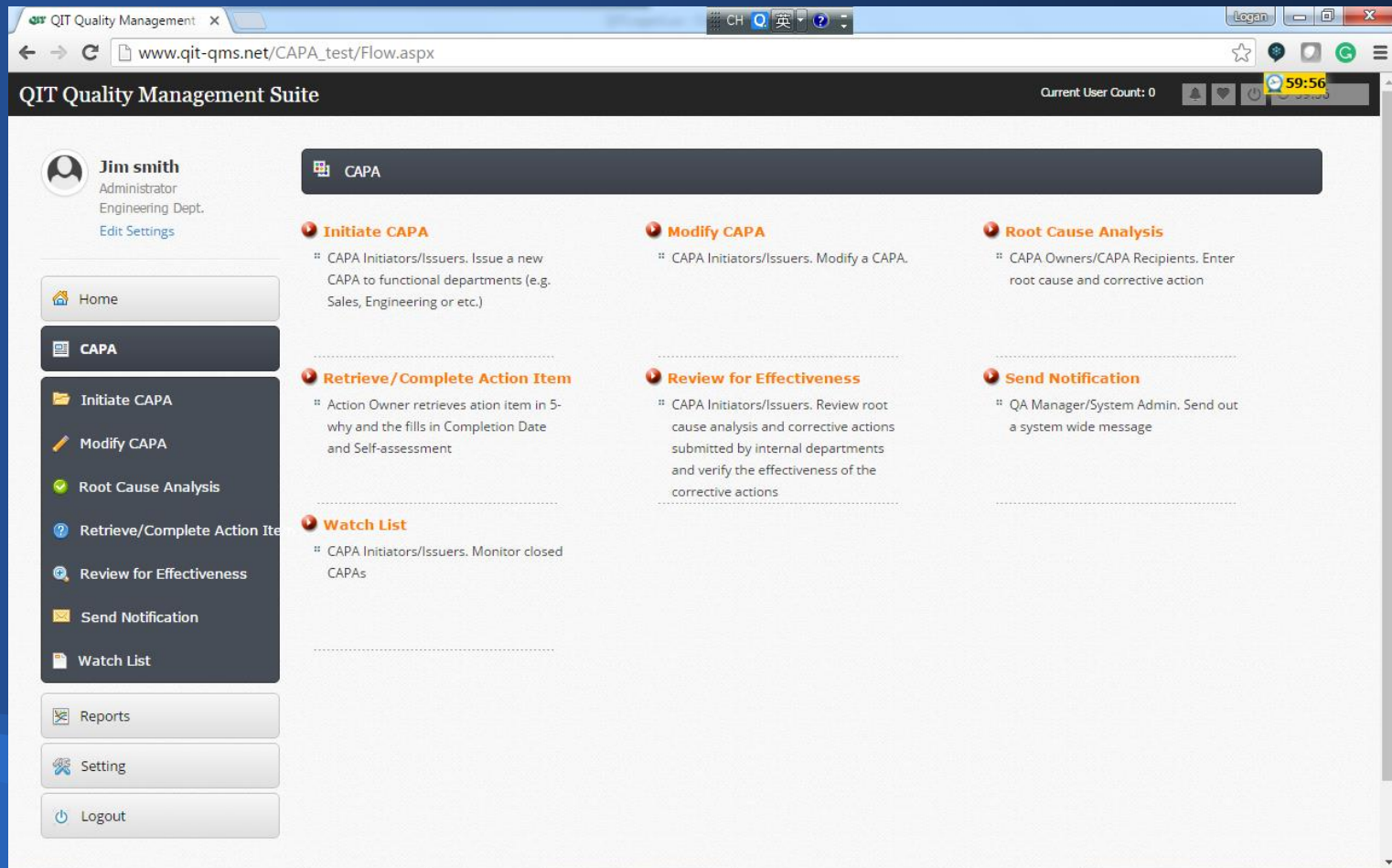
- Self-guided user-interface with explanation for each function block to save the training time and implementation efforts
- Easy-to-navigate layout

Intuitive Dashboard and To-do-List



- Intuitive Executive Summary
- Personalized To-do-list for coming due CAPAs and CAPAs waiting for root cause analysis
- System overviews in **cost and risk**

CAPA Module



- Easy-to-use self-guided user-interface with instructions on each CAPA Step e.g. Initiate → Root Cause Analysis → Review for Effectiveness for effortless implementation and smooth navigation

CAPA Form

The screenshot displays the QIT Quality Management Suite web application. The browser address bar shows the URL: `www.qit-qms.net/CAPA_test/CAR/CAPA/CAPAInitialize.aspx?IsAdd=true`. The page title is "QIT Quality Management Suite".

Left Sidebar:

- User profile: **Jim smith**, Administrator, Engineering Dept., with an [Edit Settings](#) link.
- Navigation menu:
 - Home
 - CAPA** (selected)
 - Initiate CAPA (highlighted in red)
 - Modify CAPA
 - Root Cause Analysis
 - Retrieve/Complete Action Item
 - Review for Effectiveness
 - Send Notification
 - Watch List
- Other links: Reports, Setting, Logout.

Main Content Area:

Preliminary Analysis and Action Plan

Basic CAPA Info

CAPA Number: Auto Number:	Product/Process:
CAPA Issuer: Jim smith	Product Name:
CAPA Region: MG-DOMESTIC	CAPA Issue Date: 06/16/2016
Location: --Select from list--	CAPA Category: --Select from list--
CAPA Type: --Select from list--	Response Due Date: 06/30/2016
Case Number:	Audit #:
Serial Number:	Customer Name:
Problem Solving Tool: 5-Why + 4W1H	

Possible Root Cause and Corrective Action Plan – Qualitative Analysis

Defect Description (5000 characters limit):	
Possible root cause, if known (1000 characters limit):	
Recommended Containment Action (1000 characters limit):	
Recommended corrective action (1000 characters limit):	

- Customizable CAPA form
- Built-in **risk analysis, cost analysis tools**
- All types of attachment formats e.g. Word, JPEG, CAD Dwg and etc.

Professional Root Cause Analysis Process

The screenshot shows a web browser window with the URL www.qit-qms.net/CAPA_test/CAR/Feedback/CAPAFedbackUpdate.aspx. The user is logged in as Jim Smith, Administrator, Engineering Dept. The page title is "CAPA Feedback". The "CAR Number" is CAR-16-0005. The "Root Cause Analysis" section is highlighted in red in the left sidebar. The form contains the following fields:

- Actual Containment Action:** take down 64-bit installation package and reinspect
- Containment Action Date:** [Calendar icon]
- Assign Task:** Assign Task Total 0 action(s)
- Root Cause Analysis:**
 - Who is involved with the problem?** Engineer
 - When did the problem occur?** install the program to a 64 bit system with 64 bit office
 - Where did the problem occur?** customer computer
 - How did the problem occur?** Access run time can not be installed as system will not allow 64-bit and 32-bit office at the same time
 - Why did the problem occur? (root cause summary):** Please see 5-Why analysis
 - CA 5-why:** Total 0 action(s) Please see 5-Why analysis
 - Primary Failure Mode:** Improper Procedure/Sequence
 - Problem Statement:** Did not test program in a 64-bit office environment
- Corrective Action:** Please see 5-Why analysis

- Built-in quality tools e.g. 8D, 4W1H, 5-why and Fishbone analysis to form a professional root cause analysis process
- User is able to select different combinations of quality tools for different issues and priorities. For instance: 4W1H for **low cost/risk issues** or 8D+Fishbone for **high cost and high risk issues**

Step-by-Step Root Cause Analysis Wizard

QIT Quality Management Suite

Current User Count: 0

EN ?

www.qit-qms.net/CAPA_test/CAR/Feedback/CAPAFedbackUpdateNew.aspx?IsAdd=true

59:56

Jim smith
Administrator
Engineering Dept.
[Edit Settings](#)

[Home](#)

CAPA

[Initiate CAPA](#)

[Modify CAPA](#)

Root Cause Analysis

[Retrieve/Complete Action Item](#)

[Review for Effectiveness](#)

[Send Notification](#)

[Watch List](#)

[Reports](#)

[Setting](#)

[Logout](#)

CAPA Feedback

[Containment](#) > [4W1H](#) > [CA\(5-why\)](#) > [PA](#) > [FMEA](#) > [Lessons Learned](#) > [Sent Mail](#) > [Exit](#)

[Show CAPA Details](#)

Instruction:

Please fill in actual containment e.g. segregate, red tag defectives, storing inventory and etc. If you had multiple action and wanted to assign tasks to other users, click assign task to fully manage containment actions.

Actual Containment Action:

take down 64-bit installation package and reinspect

Actual Containment Action:

Containment Action Date:

Assign Task [Assign Task](#) Total 0 action(s)

☐ This step is completed.

[Previous](#) [Next](#)

Attachment: (Max file size 10Mb)

1:	Choose File	No file chosen	Description:	
2:	Choose File	No file chosen	Description:	
3:	Choose File	No file chosen	Description:	
4:	Choose File	No file chosen	Description:	
5:	Choose File	No file chosen	Description:	
More				

- Step-by-Step Root Cause Analysis Wizard to guide user through a professional root cause analysis process e.g. 8D, 4W1H, 5-why and Fishbone Analysis
- Editable instructions to allow user sharing root cause analysis

Review for Effectiveness to close the loop

QIT Quality Management x

www.qit-qms.net/CAPA_test/CAR/Feedback/CAPAFedbackReviewUpdate.aspx

EN ?

Logan

59:47

CAR Number: CAR-16-0005

characters limit)		FMEA Completion Date:	
FMEA Due Date:		FMEA Last Modification Date:	
FMEA First Fill out Date:			

Submit Back

Lessons Learned

Lessons Learned from the problem:(2000 characters limit)	For desktop program, especially program relay on MS office, needs to be tested in 64 bit system, and 64-bit system with x86 Office, and with 64-bit Office for Office 2013 or later.
--	--

Attachment:(Max file size 10Mb)

Review for Effectiveness

Reviews/Comments and Verifications:	
Internal Comments (this field will be omitted from supplier report and CAPA report):	
Review Result:	<input type="radio"/> Accepted <input checked="" type="radio"/> Rejected Total Reject 0 Time(s)
Department:	Engineering Dept.
Reviewer:	Jim smith
Verification Due Date:	
Action Close Date:	

CAPA Watch List

Watch Reason:	
Review Date:	
Add to Watch List:	<input type="radio"/> Yes <input checked="" type="radio"/> No

Submit Back

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- Review for Effectiveness function to close the quality loop
- Special functions like **Lessons Learned** to share the best practices to the whole organization and **CAPA Watch List** function to keep closed CAPA on radar screen for long-term effectiveness review

Versatile Reports

Internal CAPA Reports

- ❖ CAPA Status Reports
- ❖ Failure Mode Reports
- ❖ Quality Cost Reports
- ❖ Department Reports
- ❖ Archive
- ❖ CAPA Reports
- ❖ Management Reports

Supplier SCAR Reports

- ❖ SCAR Status Reports
- ❖ Supplier SCAR Status
- ❖ Supply Chain Reports
- ❖ Supplier Reports
- ❖ Component Reports
- ❖ SCAR Reports

- Drill-down reports to show system performance e.g. **CAPA status, cost, risk and major issues** in annual, monthly and detailed levels
- Built-in analysis to help user identify **hidden system problems**. For instance, to monitor quality system performance user can utilize the **Department Report** to link departments and major issues and then review the trending of the issues

Versatile Reports

QIT Quality Management

EN

https://www.qit-qms.net/CAPA_test/CAR/Report/CAPAReport/CAPAStatusReport/CAPAStatusReportSummaryByYear.aspx

Jim smith
Administrator
Engineering Dept.
[Edit Settings](#)

Home

Reports

Setting

Logout

CAPA Status Report

Search

Group By: Year

Year	Open	Pending	Verification	Overdue	Closed On-time	Closed Delayed	Total	Avg Days Past Due	Avg Days Open
2016	0	0	0	5	1	0	6	37.33	49.17
2015	0	0	0	56	6	0	62	306.52	333.11
2014	0	0	0	21	1	0	22	611.68	641.32
2013	0	0	0	68	6	0	74	1009.68	1035.55
2012	0	0	0	77					
2011	0	0	0	25					
2010	0	0	0	32					
2009	0	0	0	30					
2008	0	0	0	86					
0	0	0	0	400					

Page: 1 Total Record: 9

Export To Excel Back ALL

50

QIT Quality Management

EN

https://www.qit-qms.net/CAPA_test/CAR/Report/CAPAReport/ManagementReport/ManagementReport.aspx

QIT Quality Management Suite

Current User Count: 0

Jim smith
Administrator
Engineering Dept.
[Edit Settings](#)

Home

Reports

Setting

Logout

Management Reports

Search

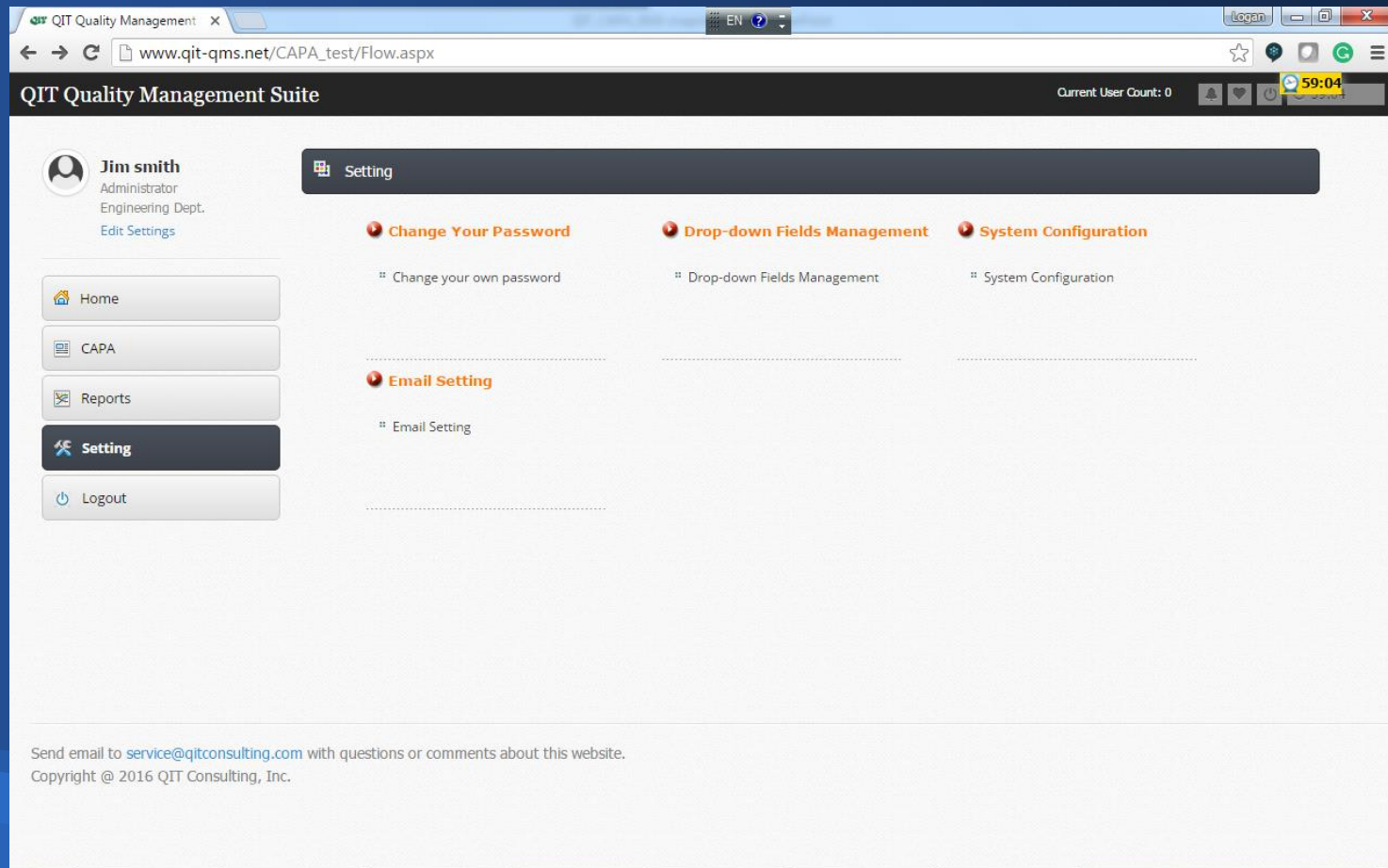
Start Date: End Date:

☒ CAPA Needs Update CA/PA ☐ CAPA Ready for Verification

Search

CAPA Number	Product Number	Issuer	Issue Date	Due Date	CAPA Type	CAPA Region	Days Past Due	Days Open
CAR-16-0002	Product	Jim smith	04/14/2016	04/29/2016	Complaint	USA	48	63
CAR-15-0049	tt	Jim smith	08/19/2015	09/19/2015	Internal audit-MINOR	USA	271	302
CAR-15-0045	tt	Jim smith	08/17/2015	09/17/2015	Internal audit-MINOR	USA	273	304
CAR-15-0044	tt	Jim smith	08/17/2015	09/17/2015	Internal audit-MINOR	USA	273	304
CAR-15-0040	123	Jim smith	05/13/2015	06/13/2015	Nonconformance	USA	369	400
CAR-15-0038	ee	Jim smith	05/13/2015	06/13/2015	Complaint	USA	369	400
CAR-15-0037	111	Jim smith	05/12/2015	06/12/2015	Vendor audit	www	370	401
CAR-15-0036	test	Jim smith	05/12/2015	06/12/2015	Vendor audit	www	370	401
CAR-15-0035	asdasd	Jim smith	05/12/2015	06/12/2015	Internal audit-MINOR	USA	370	401
CAR-15-0031	5	Jim smith	04/22/2015	05/22/2015	Vendor audit	USA	391	421
CAR-15-0027	345	Jim smith	04/22/2015	05/22/2015	Vendor audit	USA	391	421
CAR-15-0026	test	Jim smith	04/22/2015	05/22/2015	Vendor audit	USA	391	421
CAR-15-0024	test	Jim smith	04/22/2015	05/22/2015	Vendor audit	USA	391	421

Easy-to-Maintain-and-Configure System Setting



- All the drop-down fields in CAPA/SCAR forms can be managed (add/modify/remove)
- Alert emails can be customized and configured to send to different levels of users

FDA Part 11 Compliance

The screenshot shows a web browser window with the address bar displaying `www.qit-qms.net/CAPA_test/BaseInfo/AutoEmailcfg.aspx`. The page contains a list of settings for email notifications related to CAPA (Corrective and Preventive Action) verification. The settings are organized into sections with checkboxes and input fields.

Email Notification Settings:

- ☒ Send email to Issuer
- ☒ Send email to CAPA Owner
- ☐ Send email to the selected group
- ☐ Send email to project team
- ☒ Send a warning email when the CAPA Verification is due in the next days.
- ☒ Send Verification Coming Due Notification Email every days.
 - ☒ Send email to Issuer
 - ☒ Send email to CAPA Owner
 - ☒ Send email to the selected group
 - ☒ Send email to project team
- ☒ Send a warning email when the CAPA Verification is overdue.
- ☒ Send Verification Over Due Notification Email every days.
 - ☒ Send email to Issuer
 - ☒ Send email to CAPA Owner
 - ☒ Send email to the selected group
 - ☒ Send email to project team
- ☐ System sends out email automatically .
- ☐ Use system to send email .
- ☒ Use user's default email client e.g. Outlook to send email.

Enhanced System Security Setting/Part 11 Requirements:

- ☒ Use Approval Password to close CAPA/SCAR.
- ☒ Automatically reset user password every 3 months.

Buttons: Save Settings, Load Default, Auto-warning Email, Auto Email Configure, Back

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- User is able to switch to part 11 requirements for tightened system security