Sparta Academy

Sparta Systems, makers of TrackWise®, is proud to present you with an education program that will empower your software installation team members and support personnel. The Sparta Academy is composed of multiple distinct courses that will reward its students with world-class knowledge of Sparta Systems’ suite of applications, enabling your team to maximize your company’s return on investment.

Courses are held either at Sparta Systems’ corporate headquarters in New Jersey, London or in designated regional locations. Each student will be provided with a designated computer for his/her own personal use during the course sessions. Some courses are also available online via eLearning, enabling access right from your desktop. On-site group training is also available at your location upon request. Each course provides hands-on experience in a classroom setting. Training manuals are provided for each session.

It is our objective to provide you and your staff the best possible training experience in order to maximize your implementation and use of the TrackWise enterprise quality management solution. Please contact our Training Manager for more information regarding these classes and availability.

Courses include:

- Introduction to TrackWise
- Technical Fundamentals of TrackWise
- Introduction to TrackWise Configuration and Administration
- Intermediate TrackWise Configuration and Administration
- Advanced TrackWise Configuration and Administration
- Crystal Reports® Design for TrackWise
- Advanced Crystal Reports Design for TrackWise
- TrackWise QualityView for Report Developers
- TrackWise QualityView for Consumers
- Upgrading to TrackWise® 8.7
- TrackWise New Features and Enhancements
Courses include:

- Training Manager
- Audit Execution Package
- TrackWise Mobile
- Fundamentals of TrackWise Web Services
- Stratas
- 123Compliance Platform Management
- 123Compliance Complaints Management

Course descriptions and outlines are detailed on the following pages.

For further information and to obtain course schedules and locations visit us at:
http://www.spartasystems.com/services/sparta-academy

You may also contact Training at 609-807-5379 (United States) and +44 7801496487 (Europe, Middle East, Africa, and Asia)
Introduction to TrackWise®

Prerequisites: None

Audience: New TrackWise users who plan to take more advanced courses, System Administrators, IT Support Personnel, TrackWise end users

Duration: 2 Days

Course Description

This introductory course provides a thorough overview for a basic understanding of TrackWise as an event tracking and action resolution tool. It is meant for users who have no previous TrackWise experience. It is also recommended for system administrators who plan to take the Configuration and Administration curriculum. Course curriculum provides an explanation of the TrackWise components, including discussions around Admin Configuration Tools and Integration Manager. This course also includes hands-on exploration of TrackWise, explaining system functionality and capabilities. Students walk away a comprehensive understanding of how to use TrackWise from the end user perspective.

Course Topics/Outline

Overview, benefits and usage of TrackWise tools, specifically:

- TrackWise user interface navigation
- TrackWise terminology & concepts, e.g., workflow, states, activities, and locking
- Record opening
- Record progression through perform only and schedulable activities
- Reviewing family tree of records
- Data entry and updates
- Identifying next steps in a record’s workflow
- Managing user settings
- Relating records through the use of reference records
- Review of a record’s history via audit trails
- Creation of scopes and queries to locate records
- Integrated reporting using Crystal Reports and TrackWise Analytics
- Creation and utilization of Dashboard views for more effective task management
Introduction to TrackWise Supplemental Semi-Custom Event®

**Prerequisites:** Introduction to TrackWise, Student and Instructor access to company’s configured training environment

**Audience:** New TrackWise users who plan to take more advanced courses, System Administrators, IT Support Personnel, TrackWise end users

**Duration:** 1 Day

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**Course Description**

This semi-custom course supplements the Introduction to TrackWise two day course and explores TrackWise in the students’ own environment. Available in a group setting, students will delve into their company’s workflows, configuration forms and TrackWise environment to become familiar with what has been configured for their projects. Students will also perform numerous hands on exercises that involve identifying what the system administrator has made available to them in addition to exercises that coach them to think about what they will need once they start their work in TrackWise. Once students identify their individual needs with the assistance of the instructor, they will then create those items in the training environment. This course focuses heavily on the use of Scopes and Queries to locate records, reports, Dashboards and workflow and configuration form review. It is required that the students and instructor have access to the company’s training environment for this semi-custom event. The course includes creation of course materials as well as delivery.

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**Course Topics/Outline**

- Workflow review
- Configuration/Project form review
- Public scope availability and contents
- Creation of personal scopes
- Public query availability and contents
- Creation of personal queries
- User permissions related to records
- Parent child relationship review
- Single record reports
- Multi record reports
- Report Export templates and ad hoc reports to create one off reports
- Review of public dashboards
- Creation of personal dashboards
- Discussion of team needs related to scopes, queries, reports and dashboards to prepare users to return to the workplace to support their teams
Technical Fundamentals of TrackWise®

Prerequisites: TrackWise experience/Basic understanding of OS/Network/Database support

Audience: System Administrators, IT & IS Support, Help Desk, Database Administrators

Duration: 2 Days

Course Description

The Technical Fundamentals course is designed to empower IS and IT support personnel to provide efficient and complete services during and after the TrackWise implementation process. Course curriculum covers all aspects of supporting a TrackWise production environment. Within this course, students learn the technical architecture of TrackWise, system requirements and the installation process. In addition, this course covers configuration and administration of the TrackWise Web Administrator Configuration Migrator tool. Students will participate from start to finish in mastering the steps required for a successful migration.

Course Topics/Outline

- TrackWise architecture overview
- Database and Windows setup
  - Creating databases and schemas
  - TrackWise installation
  - TrackWise Utilities installation
  - Web application and underlying software installation
- TrackWise configuration migrator overview terminology and installation
- Locking down configuration using the snapshot
- Making configuration changes, migrating and verification
- Understanding what is and is not migrated
- Adding an additional environment to the migration path
- Migration best practices and troubleshooting
- Tables included in migration
- TrackWise Coordinator service setup and testing
- Troubleshooting/logs
Introduction to TrackWise® Configuration and Administration

**Audience:** System Administrators, IT and IS Support Personnel, Business Owners, Project Managers, Project Team Members

**Duration:** 5 Days

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**Course Description**

Introduction to TrackWise Configuration and Administration is a course designed to teach you how to configure a simple TrackWise project from start to finish. This course introduces the user to TrackWise configuration for a basic tracking process. Once the project has been configured, students will test it in TrackWise. In addition to configuring a project, students will learn to establish parameters for the TrackWise Coordinator®, the automatic service for executing business rules in TrackWise. This course also covers the additional responsibilities a TrackWise Administrator assumes, such as creating log-in accounts, Help Desk and monitoring tools.

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**Course Topics/Outline**

- Creation of process groups to facilitate project migration
- Introduce division and project concept
- Create a project using a 14 step methodology
- Creating a workflow
- Create data fields for configuration forms
- Define project member access to form fields and activities based on group categories
- Activate audit trail monitoring for record updates
- Define the user’s default desktop layout and create additional desktop layouts
- Define states and activities for project workflow
- Configure workflow for a project
- Test the configured project
- Configure the TrackWise Coordinator for general records upkeep
- Create user log-in accounts
- Use the Help Desk function to manage user accounts
- Use “monitor for log-off” requests and record unlocking
- Import data into Web Admin via the TrackWise Integration Manager
Intermediate TrackWise® Configuration and Administration

**Prerequisites:** Introduction to TrackWise Configuration and Administration

**Audience:** System Administrators, IT and IS Support Personnel, Business Owners, Project Managers, Project Team Members

**Duration:** 5 Days

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**Course Description**

Intermediate TrackWise Configuration and Administration goes into great detail regarding project design from a strategic, business-specific perspective. This particular course relies on pre-established business rules typical for an industry-specific tracking process.

Students will be given a work plan checklist to assist them in gathering business requirements for configuration. The course will focus on the configuration of a project. In addition, it will cover different configurable settings and address additional features of the TrackWise Coordinator used to automate many rules concerning the configuration.

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**Course Topics/Outline**

- Discuss gathering business requirements
- Identify steps to define workflow design specifications
- Introduction data field types, including grids
- Discuss and configure: schedulable activities, perform-only activities, parallel approvals
- Create notification templates
- Configure conditionally required field classes
- Utilize virtual group categories
- Validate the project created during class
- Configure TrackWise Coordinator to:
  - Administer triggers
  - Issue notifications
  - Check recurring activities
  - Generate child records and using a decision matrix
  - Use of hidden fields with counters
- Determine when (or if) records should be updated
- Auto-assign records
- Generate auto reports
- Auto-export auto reports
- Close family records by utilizing stackable admin triggers and events
- Auto alerting project members with the use of counters (Min/Max)
- Progress records based on Reference Records with use of Dynamic Queries
- Program sequence and recurring activities – Scheduling activities
- Copy child values back up to the Parent using a bottom up approach
Advanced TrackWise® Configuration and Administration

**Prerequisites:** Introduction to TrackWise Configuration and Administration, Intermediate TrackWise Configuration and Administration

**Audience:** System Administrators, IT and IS Support Personnel, Business Owners, Project Managers, Project Team Members

**Duration:** 3 Days

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Course Description

Advanced TrackWise Configuration and Administration completes the TrackWise Configuration and Administration curriculum by providing an insight into the globalization of TrackWise across multiple sites and locations. With TrackWise configured as a global application, all users will refer to one application when tracking various kinds of records. In addition, features such as auto trending, auto alerts, hidden fields with virtual group categories, and various other configurable options will be presented in a way that will enable students to get the most out of the TrackWise system.

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Course Topics/Outline

- Discuss TrackWise implementation at multiple locations
- Create multiple divisions containing multiple projects
- Define user roles to provide membership to multiple divisions/projects
- Create global dashboards to monitor records from multiple divisions/projects and distribute to users
- Configure TrackWise Coordinator to account for various time zones
- Employ TrackWise Coordinator priority groups
- Utilize multiple TrackWise Coordinator services
- Use of external fields
- Best practices with reference record fields
- Using hidden fields and virtual group categories
- Use of question fields
- Use of Coordinator for:
  - Auto trending
  - Auto alerts
  - Decision trees
  - Hidden fields
  - Auto numbering
  - Copying data from one field to another
Crystal Reports Design for TrackWise®

Prerequisites: Sparta Systems recommends Introduction to TrackWise or previous TrackWise experience/Technical Fundamentals of TrackWise/Introduction to Configuration and Administration

Audience: Any person who will be designing and developing Crystal Reports for their TrackWise implementation. This may include Project Managers, Team Members, Power End Users, Application Administrators, IS Support Personnel.

Duration: 4 Days

Course Description

The Crystal Reports Design for TrackWise course is intended to provide report writers a basic understanding of the Crystal Reports application and the TrackWise database structure. This hands-on course includes the creation of sample reports for a TrackWise implementation. A strong emphasis is placed on FDA-regulated industry examples and usage in a cGxP-regulated environment.

Course Topics/Outline

- Reporting overview
- Integration with TrackWise Web and database connectivity
- Linking tables using joins
- Adding tables to a report
- Designing multi record reports
- Grouping and sorting data within reports
- Utilizing running totals within a report
- Utilizing parameters to control report content
- Utilizing formulas to manipulate, control and calculate data
  - Date and time conversion
  - Swapping two columns of data
  - Calculate number of days open
  - Conditional display of data
  - Use of break groups to separate data
  - Management of null data result display
- Utilizing headers and footers (including headers and footers for GxP compliance)
- Development of charts and graphs
- Utilizing cross tabs for matrix development
- Utilizing the Select Expert tool to further refine data set results
- Creating single record reports
- Creating of sub-reports
- Developing an activity history report for audit trail review on a record
- Reporting on a family of records using parent-child reports
- Converting reports from one database to another
- Creating auto reports for scheduled distribution
- Troubleshooting reports
- Discuss the impact of configuration changes on reports via Views
- Discuss report validation

10
Advanced Crystal Reports Design for TrackWise®

Prerequisites: Crystal Reports Design for TrackWise

Audience: Recommended 1+ years’ experience developing Crystal Reports

Duration: 3 Days

Course Description

The Advanced Crystal Reports Design for TrackWise course is designed to expose report writers to advanced functionality in the Crystal Reports application while focusing on business-specific TrackWise scenarios.

Course Topics/Outline

- Definition and utilization of external fields
- Utilization of direct table linking related to multi-field user defined fields
  - Grid fields
  - Reference records
- Understanding single and multi-record reports filtering mechanism
- Advanced formulas and functions, including:
  - Built in functions
  - Summary functions
  - If-Then-Else logic
  - Shortcuts
  - Creating custom functions
- Evaluation time of formulas (understanding record processing before reading, while reading, while printing)
- Advanced cross-tabulation techniques
  (including forcing text labels for multi-row summary, conditional formatting, cross-tab mimic with multiple column formatting)
- Advanced charting (including drill-down reports, dual-axis charts, Top N charts, underlay functionality with charts)
- Formatting tips & tricks (including hyperlinking to PR records, alternating background colors, repeated group headers, subreports)
- Multi-pass reporting
- Cycle time, workflow and rolling date reports
- Grouping & sorting (including specified order, hierarchical grouping, summary functions)
- Variables (including running totals, shared variables, and filtering subreports to display related data content, reinitializing based on grouping)
- Formulas & functions (including concentration on built-in functions and creating custom functions)
- Control Structures—Select Case and For Loop Logic
- Arrays and Ranges—Subscripting, Variables, Logic Construct
TrackWise® QualityView for Report Developers

**Audience:** TrackWise Analytics Report Publishers and Authors

**Duration:** 4 Days

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**Course Description**

This TrackWise Analytics course is designed for the student to gain familiarity with the tools available in TrackWise Analytics to develop useful reports quickly and efficiently. There will be hands on development of simple to advanced reports and the opportunity to explore some commonly used calculations and computes. Various display and formatting options will be explored as well as discussion on the benefits of planning prior to development. The bulk of the course will focus on developing which demonstrate the ease and flexibility of TrackWise Analytics as well as show the developer advanced methods for creating reports using joins.

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**Course Topics/Outline**

- Overview of report authoring levels
- Overview of reports and charts
- Review of available report outputs
- Review of report tree and folder structure
- Thorough review of the developer’s design screen, including toolbar menu items such as formatting, slicers, layouts and page breaks
- Adding and removing report fields
- Summing columns and rows
- Grouping data
- Filtering data with simple and advanced filter options
- Creating and editing report headers and footers
- Data visualization (traffic light conditions and font stylization)
- Applying pre-formatted style sheets
- Creating virtual fields to calculate or concatenate data
- Shortcuts for data fields, work area, query area and short names
- Creating a report from a template
- Creating a report from scratch
- Creating a metric report
- Creating a chart
- Using report joins to combine two reports for a drill down report
- Creating pareto reports
TrackWise® QualityView for Report Developers (cont’d)

- Creating cycle time reports
- Execute various report design challenges to reinforce student comprehension
- Understanding how to set up and use Reportable Classes
- Defining who can run, edit, develop, share and publish reports utilizing User Permissions
- Advanced Reporting Business Scenarios:
  - Creation of Simple Comparison reporting – Charting of records for variances between the same quarter of consecutive years and comparing Open and Closed records in the same timeframe.
  - Report Joins – Combining data from separate files into one chart or report; allowing for reporting on shared parameters such as a family hierarchy or a common attribute such as date, site or type
  - Use one reportable class for Multi-level reporting – showing family records and data fields from different record types without the use of sub-reports or joins
  - Building a KPI (Key performance Indicator) Document – combing several charts and report into one document that is run with a single click; exploring drill down functionality
  - Using Defines – changing field formats and record level calculations
  - Practice with Computes – perform calculations based on a group of records
  - Formatting features – making a chart pop, highlighting data in reports and improving the overall presentation of reports
  - Function Examples – using Defines for formatting of string and dates as well as more complex calculations
  - Combined functionality to create: Calendar Style Report, Compounding Traffic Light Conditions Report, Multi-Level Drill Down Report, and Rolling Trend Dashboard Report.
TrackWise® QualityView for Consumers

Audience: TrackWise Analytics Consumers

Duration: 4 Hours

Course Description

This TrackWise Analytics Consumer course is designed to show the new Consumer Analytics user how to work with useful reports in the TrackWise environment. This course provides information on the types of reports and associated report options available to consumer users. Basic report output types and features such as report, charts, drill down reports, prompts and much more are reviewed. Additionally, the handling of data within a report for users without report design rights is included.

Course Topics/Outline

- Introduction to Analytics
- Review of report tree and folder structure
- Generating and closing reports
- Review of report types:
  - Reports and Charts
  - Reports with Prompts
  - Drill Down Reports
  - Dashboard/Document Reports
- Handling of the various output formats:
  - HTML
  - Excel
  - PDF
  - PowerPoint
  - Active Reports
  - Info Mini Report
Upgrading to TrackWise® 8.7

**Prerequisites:** Supporting TrackWise from an IT Perspective/Technical Fundamentals/Introduction to TrackWise Configuration and Administration

**Audience:** System and Local Administrators, IT Support, and Computer Systems Validation project team members

**Duration:** 2 Days

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**Course Description**

The Upgrading to TrackWise Version 8.7 course presents TrackWise System and Local Administrators, IT Support, and Computer Systems Validation project team members with a detailed explanation of the upgrade. The actual work process for conducting the upgrade from previous versions (either 7 or 8 line) to 8.7 is reviewed in hands-on exercises that will enable the student to conduct these activities independently at their own company.

In addition to the upgrade process, the class focuses on best practices for configuration management in a TrackWise 8.7 environment.

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**Course Topics**

- TrackWise 8.7 overview
- Technology overview
  - Tomcat
  - .NET framework
- Review of system requirements
  - TrackWise architecture
  - System requirements as of 8.7
- Discussion and review of next generation configuration management
  - Introduction to process groups
  - Review of historical vs. current day migration process
- Conducts hands on exercises to perform the upgrades
- Review of process group taxonomy best practices
- Review of new Web Admin and TrackWise features by TrackWise version
- TrackWise Analytics overview
New Features and Enhancements – Upgrading to TrackWise® 8.7

**Prerequisites:** TrackWise Configuration and Utilities (retired) and TrackWise Coordinator (retired) / TrackWise Experience in Configuration and Administration - Course for customers upgrading from Version 7 to Version 8

**Audience:** System Administrators, IT and IS Support Personnel, Business Owners, Project Managers, Project Team Members

**Duration:** 1 Day Course

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**Course Description**

The New Features and Enhancements – Upgrading to TrackWise 8.7 course is designed to teach TrackWise System and Local Administrators the new features and configuration changes from TrackWise Version 7 to version 8.7. The course is designed to show how process groups are created, configuration is associated to these process groups, and how they are migrated. Finally, students will be introduced to new time-saving features created for managing process group configuration in TrackWise 8.7. The class focuses on best practices for configuration management in a TrackWise 8.7 environment.

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**Course Topics**

Overview, benefits and usage of TrackWise tools, specifically:

- TrackWise 8.7 overview
- Discussion and review of next generation configuration management
  - Introduction to process groups
  - Review of historical vs. current day migration process
- Review of new Web Admin and TrackWise features by TrackWise version
- TrackWise Analytics overview
- Review of process group taxonomy best practices
TrackWise® Training Manager

**Prerequisites:** Introduction to TrackWise or TrackWise experience / Introduction to Configuration and Administration

**Audience:** System Administrators, Project Managers, Team Members and IS Support Personnel

**Duration:** 2 Days

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**Course Description**

The Training Manager course provides students with a strong understanding of the Training Manager solution from an administrator’s perspective as well as a detailed explanation of concepts and extensibility of its features. Students learn how to manage curricula, automatically schedule training records, integrate training tracking with dashboards and escalate overdue records. In addition, students learn how to integrate Training Manager with CAPA and Change Control workflows to automatically create new training records based on these processes.

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**Course Topics**

- An introduction to Training Manager concepts and terminology
- Training Manager: Core configuration review:
  - Field configuration
  - Group categories
  - Employee and training record project design
  - Workflows (employee and training records)
  - Training template configuration
  - Configuration of training requirements and schedules
  - Configuration of training curricula and curricula mapping
  - Training Manager integration with change control
- Crystal Reports® design for training records
- Advanced Topics
  - Coordinator configuration for Training Manager
  - Employee records and training template import configuration
  - Review of Dashboards relative to Training Manager
TrackWise® Audit Execution Package

**Prerequisites:** Introduction to TrackWise or TrackWise experience/Introduction to Configuration and Administration

**Audience:** System Administrators, Project Managers, Team Members and IS Support Personnel

**Duration:** 1 Day

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**Course Description**

The TrackWise Audit Execution Package course provides instruction on the configuration of the Audit Manager and offline audit components of the audit solution. It also provides practical examples of each feature in addition to the benefits and use of the feature. Upon course completion, students will be able to configure the two components of the Audit Execution Package within TrackWise.

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**Course Topics**

- Review of the audit process
- Preliminary planning
- Audit Execution Package terminology
- Integration with existing process
- Configuration of Audit Manager and offline audit forms
- Configuration of audit distribution
- Distributing audits
- Finding audit
- Using TrackWise Offline to export/import audit records
- Reviewing audit history
- Crystal Report references for Audit Execution Package
- Best practices
- Troubleshooting
TrackWise Mobile®

Prerequisites: None

Audience: Any TrackWise users who plan to take their application mobile - System Administrators, IT Support Personnel, TrackWise end users

Duration: 1 day

Course Description
This course provides an overview for a basic understanding of TrackWise Mobile as an event tracking and action resolution tool. Course curriculum provides an explanation of the TrackWise Mobile architecture, application components, including “Save Views” for Scope and Query combinations in mobile, basic functionality, FAQ’s, walkthroughs and the benefits of using a mobile device. This course will also enable users to interact with the records via mobile devices. System Administrators will learn how to enable permissions based on login accounts, so users can access TrackWise through their mobile device.

Course Topics/Outline
Overview, benefits and usage of TrackWise tools, specifically:

- TrackWise mobile app
- Web Admin configuration for projects and users
- Downloading the TrackWise app
- Accessing TrackWise Mobile on a device
- Creation and use of “My Views” to locate records in the mobile application
- Data entry and updates
- Record creation
- Action related items
Fundamentals of TrackWise Web Services®

Prerequisites: Introduction to TrackWise or TrackWise experience/Introduction to Configuration and Administration, Proficiency in Java, Comfortable working in a Java IDE, Familiar with XML

Audience: Developers

Duration: 3 Days

Course Description

The Fundamentals of TrackWise Web Services course introduces the capabilities and application of TrackWise Web Services through the use of real-life business scenarios where web services are typically implemented. Students will learn the following: background information in order to understand the business need for web services; the technologies that are typically used at a high level; how to set up and work in a development environment; and how to set up and program Inbound and Outbound web services through iterative examples that demonstrate the capabilities of the solution. Exercises throughout the course are taken from the most commonly seen web service integrations and provide a solid foundation for future web services development.

Course Topics/Outline

- Business Case for Web Services
- Installation and Environment Setup
  - Eclipse Installation and Setup
  - IWS and OWS Setup
  - Debugging
- Web Services Best Practices and Conventions
  - Code Conventions and Logging
  - Connection / Session handling
  - TrackWise Configuration
  - Parameter Files
- Inbound Web Services
  - Connection Logic
- Outbound Web Services
  - Building the Interface Contract
  - Axis2 and AXIOM
  - Search and Populate Operations
  - Working with Grids
- Putting it all Together
  - Coupling IWS and OWS
- Repeatable Process for Development
- Troubleshooting
123Compliance Platform Management

**Prerequisites:** Beginner/Intermediate Salesforce.com Administrator experience

**Audience:** System administrators, system integrators and others responsible for configuring, managing and maintaining a 123Compliance implementation.

**Duration:** 2 Days

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**Course Description**

This comprehensive hands-on course is a must for those new to the 123Compliance Platform and 123Compliance applications. This instructor led course is an intensive end-to-end exercise in configuring, implementing, and managing the 123Compliance Part 11 Platform. Participants will learn how to use the declarative “clicks not code” capabilities of the Part 11 Platform using 123Compliance applications to create workflows, setup fully compliant audit trail, and apply electronic signature capabilities.

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**Course Topics/Outline**

- 123Compliance Architecture and Application Suite
- Application Set up
  - Initial Application Setup Configuration
  - Configuring Platform Custom Settings
  - Configuring Remote Site Settings
  - Configuring Remote Access
  - 123Compliance Permission Sets
- Audit Trail Configuration
- Workflow Fundamentals
  - Creating Status, Actions, and Rules
  - Viewing Workflows
  - Multiple and Parallel Workflows
- Electronic Signatures
- Automation: Process Builder
- Utilities
  - Query Explorer
  - Configuration Deployment
  - Test Class Generation
  - Report Template Builder
  - Adding a Report Button
123Compliance Complaints Management

**Prerequisites:** Beginner/Intermediate Salesforce.com Admin Experience, 123Compliance Platform Installation and Configuration Training

**Audience:** System administrators, system integrators and others responsible for configuring, managing and maintaining 123Compliance Complaints Management application.

**Duration:** 1 Day

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**Course Description**

This comprehensive hands-on course is a must for those new to the 123Compliance Complaint Management application. This instructor led course is an intensive end-to-end exercise in configuring, implementing, and managing the 123Compliance Complaint Management application and Part 11 Platform. Participants will be introduced to Assessments, Investigations, and supported Safety and Regulatory Reporting forms using the declarative “clicks not code” capabilities of the Part 11 Platform and Complaints Management applications.

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**Course Topics/Outline**

- Complaint Management Process Overview
- Master Data Collection: Customer, Product, and Complaint Codes
- Complaint Records
  - Complaint Views
  - Creating New Complaints
- Configuring Assessments (Decision Trees)
- Configuring Investigations
- Health Hazard Evaluation Form
- Regulatory
  - EMDR Setup and Configuration
  - Submitting Electronic Reports
  - MEDDEV Form and Functionality
  - Canadian and Australian Report Forms