Course Purpose: To teach developers of FDA regulated products and services field-proven ways and means to realize the benefits of Agile-driven development in a way that also satisfies the reality of regulatory requirements.

Format & Duration: Classroom; 2-days (plus certification exam).

Who Should Attend: Developers, program managers, testers, quality assurance, and regulatory/compliance professionals of products/services that are regulated by the Food and Drug Administration (FDA), and thus also governed by a Quality Management System (QMS), and who are, or are considering, employing an Agile development framework (e.g., Scrum, SAFe, etc.).

Participant Prerequisites

- Certified Scrum Master (CSM), or equivalent caliber proficiency with your organization's chosen Agile framework (e.g., Scrum, SAFe, etc.).
- Familiarity with your company's QMS.

Course Background

- Agile methods DO NOT CONFLICT with the requirements of FDA regulations, ISO 13485, IEC 62304, or other related standards and guidance.
- Agile methods OFTEN CONFLICT with the company's QMS.
- QMS procedures must be adapted for Agile methods; likewise, Agile methods must be adapted for compliance.

Course Outcomes

- Participants will be able to apply Agile methods in ways that bring the benefits of Agile while satisfying FDA regulations and regulatory expectations.
- Participants will understand the intent of regulations so they can be satisfied in a pragmatic way.
- Participants successfully completing the class and achieving a passing score on the subsequent exam, will earn their CARS™ certification.

Course Outline

- The Rules of the Game: Overview of Medical Device Regulations and Standards.
- Agile Foundations for Design Control.
- Your System: Tailoring your process and Agile practices to match the System/Product you develop
- Aligning Agile with the Regulations and Standards.
- Change Management.
- Definition of Done.
- Any Sequence Will Do
- Roles.
- Requirements & Backlogs.
- Aligning with a Linear Business Process.