The SASI Clinical Research QUALITY ACCELERATOR PROGRAM

Developed for SASI by the Quality Management Institute

Clinical Research - Quality Accelerator Program (QAP)

The Clinical Research Quality Accelerator Program is designed to "accelerate" the CRS's validation of its capacity to conform to and sustain its conformance to the SASI-QMS:2020-1 Standard. Accreditation is not just an event. It is a process that begins with validation of conformance to the requirements of the Standard and continues in the daily demonstration of a high-performing work culture rooted in quality management fundamentals. The cornerstone of conformance to the Standard is the commitment of the CRS "to quality management and a sustaining work culture." This program will verify, validate, and/or remediate your team's human values and skills, process knowledge and application of technologies via a comprehensive curriculum of education, collaboration, and team building.

With this jointly held subject matter expertise as a foundation, we'll show you how to maximize your strengths and apply work-process analysis techniques that will leverage your team into reliable high performance. The QAP curriculum increases the capacity of the human to be a reliable partner with technologies in an intelligent system of quality management. And, you will have the capacity to design, develop, plan and budget with greater certainty and predictability. QAP provides a competitive advantage for clinical research leadership with measurable increases in productivity and on-time, lean and profitable deliverables. And more importantly, when the safety and security of lives are at stake, the SASI QAP should be your project partner.

QAP is supported by online self-paced training and a secure testing center to assure competency. It is also supported by SASI staff and the QMI faculty to assist in fully integrating the people, processes and tools required for success. We will help you design a program that fits your development needs and your budget. Following are descriptions of the training options and modules. For more information, contact SASI at admin@sasi-accreditation.org

The Clinical Research Quality Manager (CRQM) "Professional" Certification

for Clinical Research Leaders, Managers and Leadership Development. Modules 1 through 8 A Comprehensive Review and Learner Assessment of QM Skills and Values, Project Management Concepts and Administrative Principles. (Professional Certification and Transcript)

CRQM Module: 1 – ZERO DEFECTS ATTITUDE

A Zero Defects Attitude is not just a concept for eliminating defects in a product or service; it is an attitude of the heart. Similar to the "pride of workmanship," it represents a desire to do things right, every time we take action. It is not an attempt to achieve perfection but a commitment to make each customer's experience as close to what was promised as possible. The Learner will gain specific knowledge of:

- The Eight Attributes of a Quality Manager as a foundation for achieving all course objectives.
- QM methods, values and language that will enable learning throughout the course lessons.
- How quality is connected with and controls profitability in all disciplines and venues.

CRQM Module: 2 – VOCATIONAL CERTAINTY

Vocational Certainty[™] is a measure of our faithfulness to our career agenda. When we have been disciplined about developing our skills and talents, we can acquire the self-esteem and confidence that accompanies earned success. Vocational Certainty[™] challenges us to become equipped by education, training and experience to perform effectively and grow in leadership. The Learning objectives are.

- How to identify a person's vocational strengths, weaknesses, character and personality.
- How to define and achieve reasonable standards for excellence.
- Human motivation in the workplace and how to increase productivity and prevent errors.
- How to define obstacles to workplace efficiency and calculate the costs to eliminate them.

CRQM Module: 3 – PROCESS QUALITY

Process Quality is a measure of our mastery of planning and budgeting disciplines. Applying the QM-WPA Project Management principles will enable a person with good ideas to bring organization to his or her work, improve their communications skills and establish the influence that is critical to career growth. The Learner will gain specific knowledge of:

- The concepts of Work Process Analysis and how to apply it to create reliable business solutions.
- How to evaluate ideas for a product or service improvement and use lists to manage them.
- How to research the design and demand for a project and take reasonable development actions.
- How to calculate the resources for implementing a project and create a pro-forma budget.
- How to eliminate the guessing and unfounded financial assumptions that create project failures.
- How to convert research and design data into reliable steps for project implementation.
- How to accurately extract Risk-Based Quality Management derivatives with WPA actions.

CRQM Module: 4 – ADMINISTRATIVE CONSISTENCY

Administrative Consistency is a measure of our attention to details. When people think of managing details, they often picture a bookkeeper or a shipping clerk making sure all of the names and numbers match on a shipping list. The Learner will gain specific knowledge of:

- The communications skills required to establish reliable business processes and relationships.
- Applying "due diligence" to workplace details and the leadership skills required to manage risks.
- Five methods for monitoring defects and the business metrics to isolate and eliminate the causes.
- The Four Absolutes for Choosing Reliable People and how to unify around common goals.

CRQM Module: 5 - EXECUTIVE CREDIBILITY

Executive Credibility is a measure of our sincerity and skill with people. Sincerity comes naturally from the heart. But skills can be sharpened and improved. By adding QM values and methods to your routines, people will gain confidence in your leadership, especially when you take time to listen to them and give them clear, competent answers. The Learner will gain specific knowledge of:

- The Three Relational Principles for Creating an Open and Accountable Work Culture.
- How to manage the consequences of personal behaviors rooted in fear, insecurity and pride.
- How to measure the reliability of information, test and prove the facts, and act responsibly.
- How personal authenticity in workplace relationships can create opportunities for great success.

CRQM Module: 6 – PERSONAL AUTHENTICITY

Personal Authenticity is a measure of our resolve to be consistent with our customers and coworkers. There are indicators of consistency in leadership all around us. They're recognized by how we routinely depend upon products and services that support our personal or business lifestyle. But somewhere an authentic leader is working diligently to make our experience feel normal. The Learner will gain specific knowledge of:

- Applying due diligence to workplace details and the leadership skills required to manage risks.
- Making workplace decisions by applying the "Scientific Method" to personnel and process issues.
- The impact of poor workplace ethics on an enterprise, its customers and shareholders.

CRQM Module: 7 – ETHICAL DEPENDABILITY

Ethical Dependability is a measure of our trustworthiness in practical matters. It is clearly indicated in the ways we handle money and exercise our organizational authority. It is also measured by whether or not people turn to us when they want things to work right, run on time, and be there when they are needed. The Learner will gain specific knowledge of:

- The communications skills required to establish reliable business processes and relationships.
- The causes and business costs associated with workplace negligence and how to avoid them.
- How to identify and manage the personal factors that complicate business judgments.

CRQM Module: 8 - CREATES A QM-KEEPING-THE-PROMISE CULTURE

The openness and collegiality of a QM Keeping the Promise Culture is the most effective model for leadership because it is predicated upon recognizing one another's strengths and finding the most effective solutions to problems. The Learner will gain specific knowledge of:

 How to naturally model the values of a QM-Keeping the Promise Culture and become an influential leader and change agent.

