IAAE®
International Academy of Automation Engineering®

IAAE®

2021 COURSE CATALOG

CONTINUE

www.myiaae.org

"IAAE® has a clear vision for the future of education and training on automation in the life sciences industry. They are actively working with universities, consortia, and life sciences companies to make things happen.

As a member of the Life Sciences Advisory Board, I'm always challenged to help find ways to bring relevant automation education to university students, as well as online and hands-on training to industry professionals.

There's a real need for life sciences companies to be able to hire new graduates with the right skills and/or provide external training. The current model of on-the-job training isn't efficient for anyone."

Rick Lawless, Manager, Training & Development, KBI Biopharma
and IAAE® Life Sciences Advisory Board member

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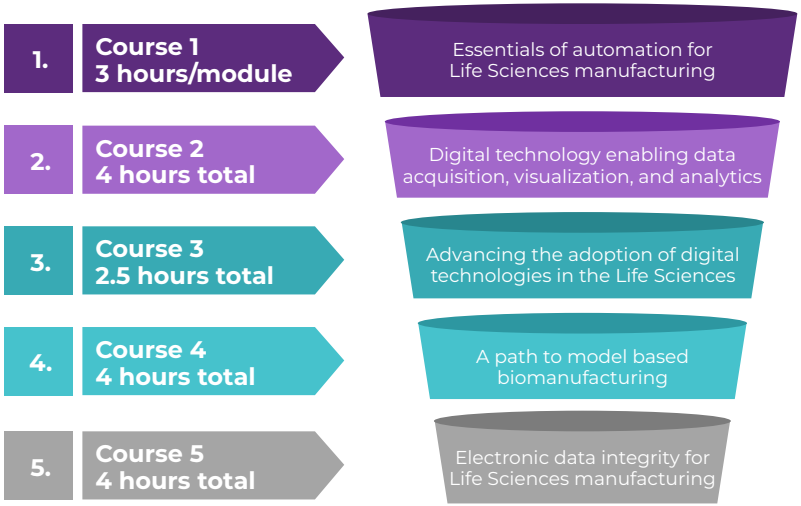
OVERVIEW

WHAT IS THE PURPOSE OF THIS COURSE CATALOG?

This course catalog serves to outline the educational materials currently offered by the IAAE®. The IAAE® offer educational materials that are product agnostic and not training materials that have a focus on specific products and platforms. Courses shown do not need to be taken in a specific sequence, and it is highly unlikely that any one individual would benefit from taking all materials offered. The IAAE® recommend an individual development plan be created for each participant and that a group of participants engage in a coordinated program over either eight or twelve months.

At the moment, there are five IAAE® courses available, containing various modules within each that cover a wide range of topics.

Every module has specific aims and learning objectives, described in detail in this catalog, which shed light on the overall content within each and help one understand the target audience.



SAMPLE COURSE SEQUENCE ONLY

click on a section on the left to quickly navigate this catalog

COURSE 1: ESSENTIALS OF AUTOMATION FOR LIFE SCIENCES MANUFACTURING (37 MODULES, ~3 HOURS/MODULE)

The modules developed by the IAAE® within this online course fully align to Tier 5 – Industry-Sector Technical Competencies within the Automation Competency Model (pictured and described in the next two pages) developed by the US Dept. of Labor, Employment and Training Administration, with input from the Automation Federation.

The 37 online modules within the course (approximately 3 hours seat time each) cover the topics within the Tier 5 subject areas as pictured on the next page.

These online materials have already been reviewed by senior automation SMEs within Merck and Genentech and have also received very positive feedback from many of the participants at GSK, Takeda, Biogen, and other organizations.

IAAE® Essentials of Automation for Life Sciences Manufacturing *(online)*

A Context of Automation
010. Introduction to Automation for Life Sciences Manufacturing

B Measurement, Sensors, and Actuation
020. Basic Process Instrumentation
030. Analytical Instrumentation
040. High Performance Sensors
050. Valve Actuation
060. Motor and Drive Control
070. Electrical Planning and Installation

C Control
080. Continuous and Process Control
090. Discrete and Sequencing Control
100. Batch Control
110. Building Automation Systems and HVAC
120. Motion Control
130. Control System Types and Architectures
140. Documentation for Automation Engineering
150. Industrial Robotics
160. Programming Languages for Automation Systems
170. Visualization and Display

D Communication, Integration, and Software
180. Network Configuration Principles
190. Introduction to Industrial Digital Field Protocols
200. Overview of Industrial Communication Protocols
210. Introduction to Manufacturing Operations Management
220. Introduction to Manufacturing Execution Systems
230. Database Management
240: Introduction to Historian Software Platforms

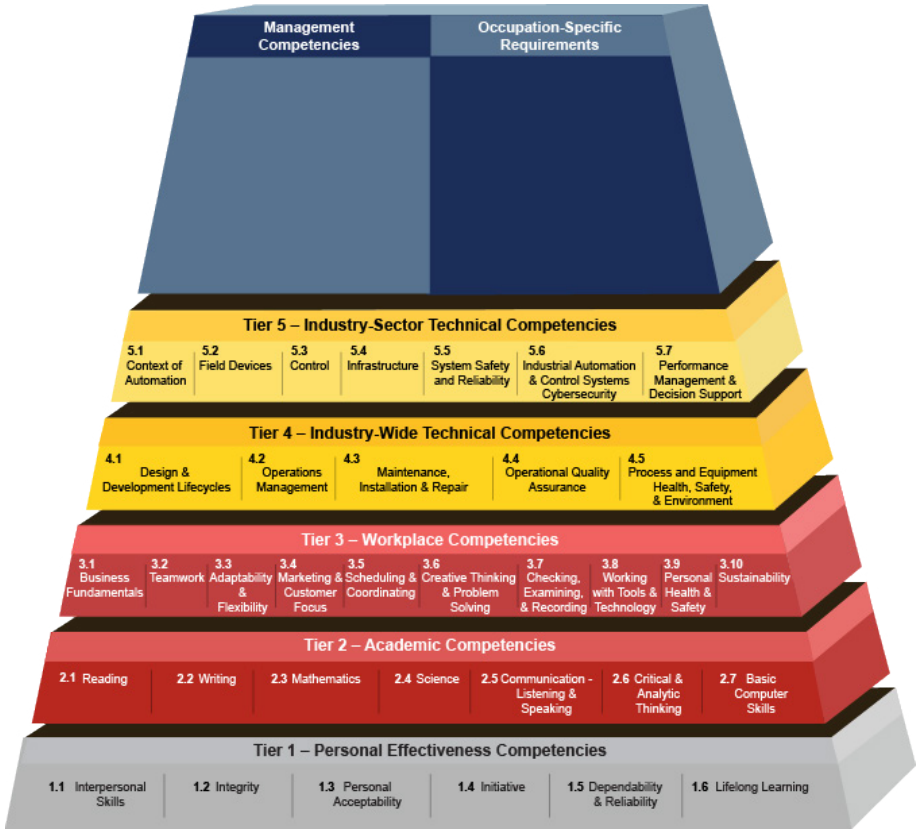
E Automation System Safety and Reliability
250. Alarm Management
260. Reliability
270. Machine and Process Guarding
280. Manufacturing Safety
290. Safety Controller Equipment and Safety Standards
300. Good Automated Manufacturing Practice

F Industrial Control Systems Cybersecurity
310. Introduction to Manufacturing Cybersecurity
320. Operational Technology Architectures
330. Networks
340. Operating Systems
350. Telecommunications
360. Information Assurance
370. The Security Lifecycle

Navigation

AUTOMATION COMPETENCY MODEL

Focus is on Tier 5 - Life Sciences Industry Sector



For more information on this model follow this link

AUTOMATION COMPETENCY MODEL IN MORE DETAIL

The Automation Competency Model is a resource that provides a comprehensive collection of the competencies - the knowledge, skills, and abilities - required in the automation industry. The competencies are described using examples of the critical work functions and the technical content common to the industry. A competency describes a behavior but does not describe a level of performance, as different workers will need different levels of competence to complete their job functions.

The model is depicted in a graphic consisting of several tiers. Each tier is comprised of blocks that group the knowledge, skills, and abilities essential for successful performance in the industry. At the base of the model, the competencies apply to a large number of occupations and industries. As a user moves up the model, the competencies become industry- and occupation-specific. The pyramid shape does not imply that competencies at the top are at a higher level of skill. Instead, the model's shape represents the increasing specialization and specificity in the application of skills.

Tiers 1 through 3, called Foundation Competencies, form the foundation needed to be ready to enter the workplace.

Tier 1 – Personal Effectiveness Competencies represent personal attributes or "soft skills". Essential for all life roles, personal effectiveness competencies are generally learned in the home or community and reinforced at school and in the workplace.

Tier 2 – Academic Competencies are critical competencies primarily learned in a school setting. They include cognitive functions and thinking styles, and are likely to apply to most industries and occupations.

Tier 3 – Workplace Competencies represent motives and traits, as well as interpersonal and self-management styles honed in the workplace. They are generally applicable to a large number of occupations and industries.

Tiers 4 and 5 show the cross-cutting industry-wide technical competencies needed within an industry wherein a worker can move easily across industry sub-sectors. Rather than narrowly defining a single occupational career ladder, this model supports the development of an agile workforce.

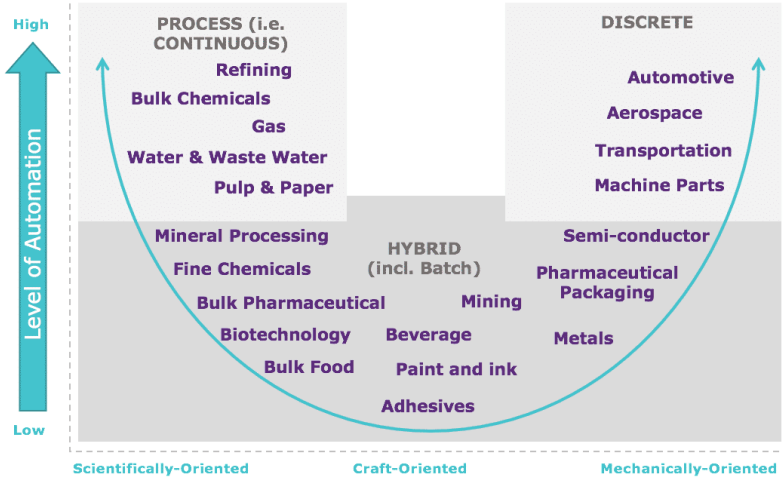
Tier 4 – General Technical Competencies represent the basic knowledge and skills that are common across automation sectors.

Tier 5 – Specific Technical Competencies represent advanced competencies that are specific to automation.

The upper tiers represent the occupational specialization within the industry.

SOURCE: This text is from the Automation Competency Model document (as updated in July 2018).

MODULES AND LEARNING OBJECTIVES

Module	Learning Objectives
Section A: Context of Automation (Module 010)	
Module 010 Introduction to automation for Life Sciences manufacturing	This introductory module aims to introduce you to automation for Life Sciences manufacturing by asking: - What is the Life Sciences industry? - What is automation? - What is automation for Life Sciences manufacturing? - What standards relate to automation systems design and operation? - What is the future of automation for Life Sciences manufacturing? 

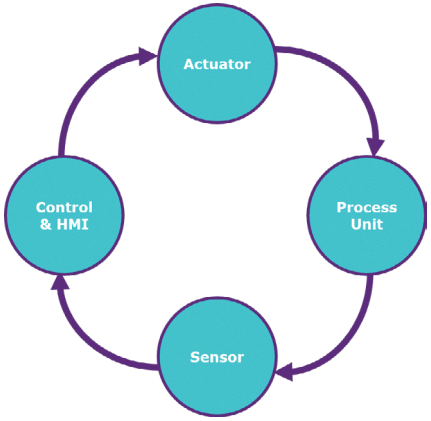
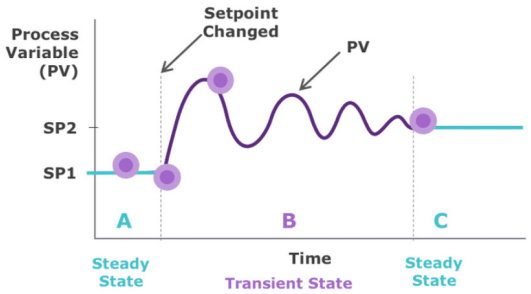
MODULES AND LEARNING OBJECTIVES

Module	Learning Objectives
Section B: Measurement, Sensors, and Actuation (Modules 020-070)	
Module 020 Basic Process Instrumentation	This module aims to give you an introduction to measurement and basic process instrumentation. The learning objectives of this module are that you will be able to explain measurement of: • Flow • Temperature • Pressure • Level 

MODULES AND LEARNING OBJECTIVES

Module	Learning Objectives
Section B: Measurement, Sensors, and Actuation (Modules 020-070) *continued*	
Module 030 Analytical Instrumentation	This module aims to give you an introduction to the purpose of analytical instrumentation and the design frameworks and tools that are adopted when specifying and implementing this category of instrumentation for improved process control. The learning objectives of this module are that you will be able to explain: • the Quality by Design (QbD) process • the analyzer sampling type process • the analytical instrument technology selection process • the steps in choosing and installing a sample conditioning system • the importance of maintaining analytical instruments and analyzers • at a high level what a Process Analytical Technologies framework is
Module 040 High Performance Sensors	This module aims to give you an introduction to high performance sensors and specialized technologies/systems for measurement. The learning objectives of this module are that you will be able to explain: • Some of the application needs for high performance sensors • Auto-identification • Vision systems
Module 050 Valve Actuation	This module aims to give you an introduction to the types of valve actuation as well as various types of valves used for automated control. The learning objectives of this module are that you will be able to explain: • The purpose of actuation • Electric actuation • Hydraulic actuation • Pneumatic actuation • A variety of valve types
Module 060 Motor and Drive Control	This module aims to give you an introduction to motor and drive control. The learning objectives of this module are that you will be able to explain: • Concepts of motor and electronic drive control

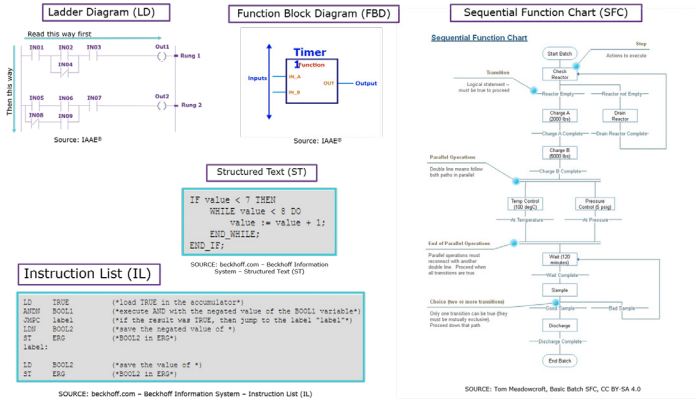
MODULES AND LEARNING OBJECTIVES

Module	Learning Objectives
Section B: Measurement, Sensors, and Actuation (Modules 020-070) *continued*	
Module 070 Electrical Planning and Installation	This module aims to give you an introduction to electrical installations. The learning objective of this module is that you will be able to explain: • The electrical installation requirements for an automated manufacturing plant
Section C: Control (Modules 080-170)	
Module 080 Continuous and Process Control	This module aims to give you a clear understanding of continuous process control. The learning objectives of this module are that you will be able to explain: • Continuous process characteristics • Feedback control & what loop tuning is • The principles of advanced regulatory control  

MODULES AND LEARNING OBJECTIVES

Module	Learning Objectives
Section C: Control (Modules 080-170) *continued*	
Module 090 Discrete and Sequencing Control	This module aims to give you a clear understanding of discrete and sequencing control. The learning objectives of this module are that you will be able to explain: • The concepts behind discrete/sequential control • The basic functional structure of a Programmable Logic Controller • Some of the textual and graphical languages used to program automated systems
Module 100 Batch Control	This module aims to give you a clear understanding of the concepts behind batch control The learning objectives of this module are that you will be able to explain: • batch process and batch processing configurations • types of batch control, including basic control, procedural control and coordination control • batch control and the S88 Standard • different types of batch recipes and the information required in a recipe
Module 110 Building Automation Systems and HVAC	This module aims to give you a clear understanding of the basics of Building Automation Systems (BAS) - including Heating, Ventilation, Air Conditioning (HVAC) for the Life Sciences industry with a focus on the regulatory requirements using design examples. The learning objectives of this module are that you will be able to explain: • The different design requirements for office spaces and mission critical spaces such as spaces for manufacturing, lab, and warehouse, which may be called Good Manufacturing Practice (GMP) spaces • HVAC equipment • BAS architectures and components • HVAC/BAS project lifecycle • Popular BAS vendors and products

MODULES AND LEARNING OBJECTIVES

Module	Learning Objectives
Section C: Control (Modules 080-170) *continued*	
Module 120 Motion Control	This module aims to give you a clear understanding of the concepts behind motion control. The learning objectives of this module are that you will be able to explain: • the different types of motion control used to automate machine and processes • some basic steps to follow when designing motion control systems
Module 130 Control System Types and Architecture	This module aims to introduce you to different control system types and the various architectures, hardware, and communication protocols used to implement them. The learning objectives of this module are that you will be able to recognize the features and discuss the benefits of each of the following: • Distributed Control System (DCS) • Process Automation System (PAS) • Programmable Automation Controller (PAC) • Programmable Logic Controller (PLC) • Supervisory Control and Data Acquisition (SCADA) • Embedded Systems 

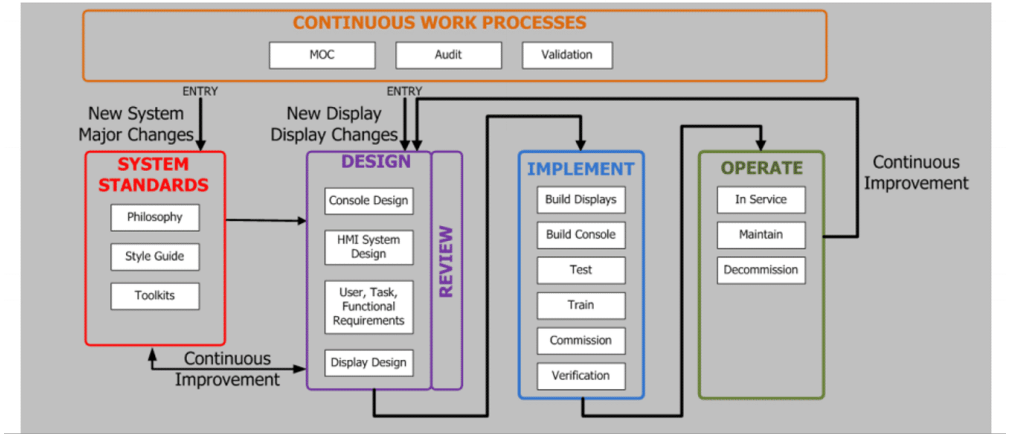
MODULES AND LEARNING OBJECTIVES

Module	Learning Objectives
Section C: Control (Modules 080-170) *continued*	
Module 140 Documentation for Automation Engineering	This module aims to introduce you to control system documentation and the significance of different document types used to ensure project success. The learning objectives of this module are that you will be able to explain: • The need for a variety of documentation types needed to support the life-cycle of automation projects. • The value of documentation to capture project information as well as communicate information between team members. • Understand the benefit and intended use of each main document type.
Module 150 Industrial Robotics	This module aims to give you a clear understanding of the concepts behind industrial robotics. The learning objectives of this module are that you will be able to explain: • How robots are utilized in industrial applications There are 2 performance objectives for this module: 1. Demonstrate an understanding of the variety of applications for industrial robotics 2. Research and make a recommendation for a suitable industrial robot for a set of stated requirements 

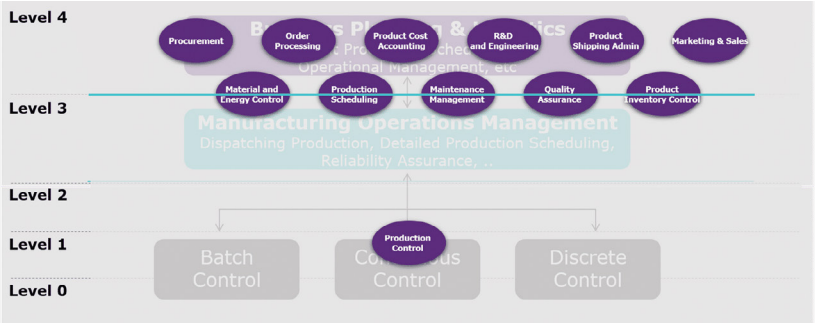
MODULES AND LEARNING OBJECTIVES

Module	Learning Objectives
Section C: Control (Modules 080-170) *continued*	
Module 160 Programming Languages for Automation Systems	This module aims to give you a clear understanding of automation programming languages. The learning objectives of this module are that you will be able to: • Explain the purpose of the IEC 61133-3 standard • Identify each of the programming languages defined: - Ladder Diagram (LD) - Function Block Diagram (FBD) - Sequential Function Chart (SFC) - Instruction List (IL) - Structured Text (ST) • Discuss key features of each language • Explain future trends in programming
Module 170 Visualization and Display	This module aims to give you a clear understanding of the concepts relating to the visualization of automated processes, best practices relating to the design of Human Machine Interfaces (HMIs), and the life-cycle management of such interfaces. The learning objectives of this module are that you will be able to explain: • the purpose of Human Machine Interfaces (HMIs) • why certain HMI interfaces are far better than others • the basics of human factors engineering & ergonomics relating to situational awareness and sensory limits • how HMI applications are evaluated in terms of display styles and performance factors • HMI system management and lifecycle stages

MODULES AND LEARNING OBJECTIVES

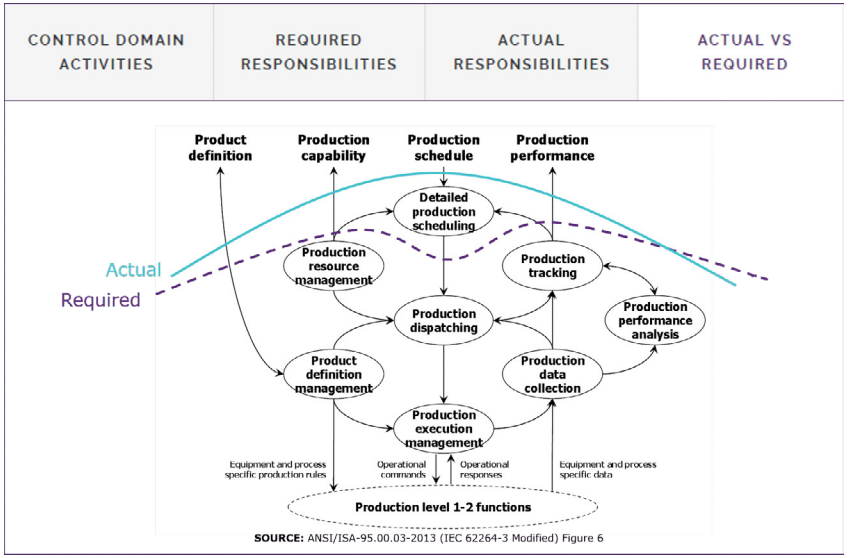
Module	Learning Objectives
Section D: Communication, Integration, and Software (Modules 180-240)	
Module 180 Network Configuration Principles	This module aims to give you a clear understanding of the principles behind industrial networks and network configuration. The learning objectives of this module are that you will be able to explain: • the benefits of both cable and wireless networks • network component configuration • network diagnostics and network management  SOURCE: Section 4 - ANSI/ISA-101.01-2015.
Module 190 Introduction to Industrial Digital Field Protocols	This module aims to give you a clear understanding of the principles behind industrial digital field protocols and the implementation of these communication protocols between field equipment, digital controllers, and various software suites. The learning objectives of this module are that you will be able to explain: • Why digital field protocols are necessary for industry applications • The main protocols used in industry such as Foundation Fieldbus, HART, Profibus, and Ethernet/IP

MODULES AND LEARNING OBJECTIVES

Module	Learning Objectives
Section D: Communication, Integration, and Software (Modules 180-240) *continued*	
Module 200 Overview of Industrial Communication Protocols	This module aims to give you a clear understanding of the principles behind industrial digital field protocols used to link process control and plant automation modules. The learning objectives of this module are that you will be able to explain: • why industrial communication protocols are necessary for industry applications • the main protocols used in industry such as BACnet, LonWorks, OPC, and Ethernet TCP/IP
Module 210 Introduction to Manufacturing Operations Management	This module aims to introduce you to the concepts behind Manufacturing Operations Management (MOM) and how it relates to other concepts such as digital thread, digital twin, and Manufacturing Execution Systems. The learning objectives of this module are that you will be able to define or describe: • Manufacturing Operations Management activities • The typical business drivers for integration of systems • The six parts of the International Society of Automation (ISA) ISA-95 standard • The level 3-4 boundaries and information flows • Manufacturing Operations Functions • Information flows from the enterprise domain functions to the control domain functions and vice versa 

MODULES AND LEARNING OBJECTIVES

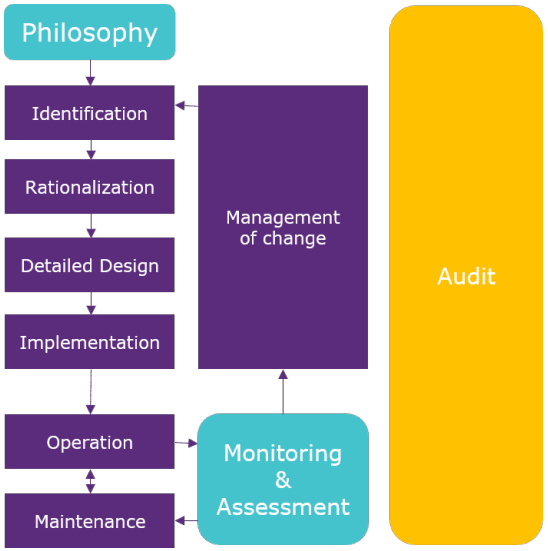
Module	Learning Objectives
Section D: Communication, Integration, and Software (Modules 180-240) *continued*	
Module 220 Introduction to Manufacturing Execution Systems	This module aims to introduce you to Manufacturing Execution Systems and how decisions are made regarding which systems should be governed by the control domain (i.e. Production and Operations) or the enterprise domain (i.e. Business). The learning objectives of this module are that you will be able to explain: • the variety of computer systems used for manufacturing • how control responsibility can be defined • sample lines of technical integration (ie. how systems will be implemented along boundary lines) • what typical MES vendors have to offer • enterprise asset management



MODULES AND LEARNING OBJECTIVES

Module	Learning Objectives
Section D: Communication, Integration, and Software (Modules 180-240) *continued*	
Module 230 Database Management	This module aims to give you an overview of the concepts relating to databases and database management. The learning objectives of this module are that you will be able to explain: • key advantages of a Database Management System (DBMS) • the need for data security and data quality • the basic principles of designing databases • interacting with databases to run and generate reports • special requirements of real-time databases • key activities to maintain databases
Module 240 Intorduction to Historian Software Platforms	This module aims to give you a clear understanding of the purpose of historian software as well as examples of what historian software vendors offer. The learning objectives of this module are that you will be able to explain: • the purpose of historian software • the typical sources of data for a historian • a number of example historian solutions available in the market

MODULES AND LEARNING OBJECTIVES

Module	Learning Objectives
Section E: Automation System Safety and Reliability (Modules 250-300)	
Module 250 Alarm Management	This module aims to give you a clear understanding of the concepts relating to alarm system management. The learning objectives of this module are that you will be able to explain: • Alarm system management • HMI design and performance metrics as they relate to alarm systems After this module you should be able to analyze and determine the need for design changes or additional equipment to improve safety with regards to the following: 1. Alarm prioritization 2. Performance metrics 3. HMI design 

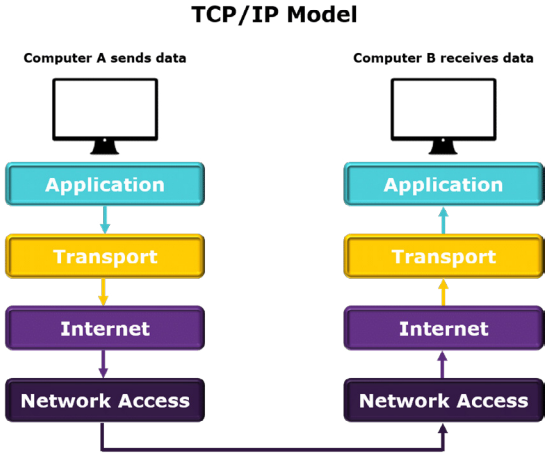
MODULES AND LEARNING OBJECTIVES

Module	Learning Objectives
Section E: Automation System Safety and Reliability (Modules 250-300) *continued*	
Module 260 Reliability	This module aims to give you a clear understanding of the concepts behind reliability. The learning objectives of this module are that you will be able to explain: • Measurements of successful operation • Dangerous and safe failure modes • Types of redundancy
Module 270 Machine and Process Guarding	This module aims to give you a clear understanding of the concepts behind machine and process guarding. The learning objectives of this module are that you will be able to explain machine and process guarding in terms of: • design considerations • laws and regulations • protection levels • risk analysis
Module 280 Manufacturing Safety	This module aims to give you a clear understanding of the concepts relating to manufacturing safety in general. The learning objectives of this module are that you will be able to explain: • manufacturing safety for process, discrete, and hybrid processes • hazard and risk analysis • the activities carried out in the safety life cycle
Module 290 Safety Controller Equipment and Safety Standards	This module aims to give you a clear understanding of the concepts behind safety controller equipment as well as key safety standards and best practices. The learning objectives of this module are that you will be able to understand • the purpose of Safety PLCs and Safety Instrumented Systems (SIS) • equipment for use where explosive concentrations might be present • installation design for hazardous areas • some OSHA, IEC and ISO safety standards

MODULES AND LEARNING OBJECTIVES

Module	Learning Objectives
Section E: Automation System Safety and Reliability (Modules 250-300) *continued*	
Module 300 Good Automated Manufacturing Practice	This module aims to give you a clear understanding of the concepts and benefits of Good Automated Manufacturing Practice, or GAMP for short. The learning objectives of this module are that you will be able to: • list some of the key drivers for GAMP 5 • define Life cycle phases and use of a general project model • explain how GAMP supports Quality Risk Management • discuss regulated company activities • recognize supplier activities • explain the GAMP Validation Model approach for a Configured Product (Note: The GAMP V Model should not to be confused with GAMP 5) • understand the GAMP V Model approach for a Custom Application
Section F: Industrial Control Systems Cybersecurity (Modules 310-370)	
Module 310 Introduction to Manufacturing Cybersecurity	This module aims to give you a clear understanding of the concepts behind cybersecurity, with a focus on Industrial cybersecurity. The learning objectives of this module are that you will be able to explain: • cybersecurity strategies including CIA Triad, Defense in Depth, Principle of Least Privilege, and the User. • the relevant Policies and Procedures in Information Technology (IT) & Operational Technology (OT). • the security life-cycle, defining the different stages. • how the human factor influences cybersecurity strategies.

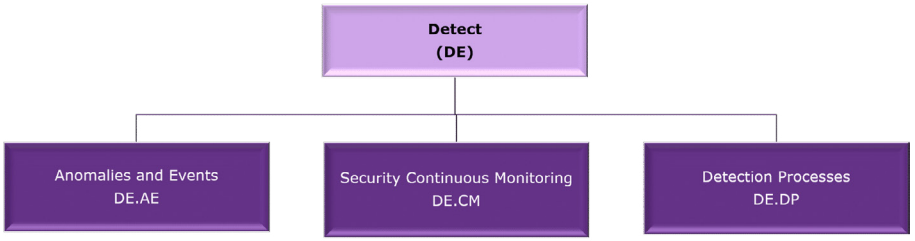
MODULES AND LEARNING OBJECTIVES

Module	Learning Objectives
Section F: Industrial Control Systems Cybersecurity (Modules 310-370) *continued*	
Module 320 Operational Technology Architectures	This module aims to give you a clear understanding of the concepts behind Operational Technology (OT) and OT architectures. The learning objectives of this module are that you will be able to explain: • typical OT architecture, considering the Purdue model and ISA-95 Level definitions • the layers of operation of communication protocols, comparing the ISO model with the TCP/IP model • what the drivers of OT systems are
Module 330 Networks	This module aims to give you a clear understanding of the concepts behind Networks, with a focus on Industrial cyber security. The learning objectives of this module are that you will be able to explain: • Introduction to Industrial Networks • Separation of OT and IT network components • Zones, Conduits and Security levels 

MODULES AND LEARNING OBJECTIVES

Module	Learning Objectives
Section F: Industrial Control Systems Cybersecurity (Modules 310-370) *continued*	
Module 340 Operating Systems	This module aims to give you a clear understanding of the concepts behind Operating Systems with a focus on Industrial cyber security. The learning objectives of this module are that you will be able to explain: • Operating systems • Patch management
Module 350 Telecommunications	This module aims to give you a clear understanding of concepts behind telecommunications and data transmission. The learning objectives of this module are that you will be able to explain: • Data transmission media • Serial and Parallel Data Transmission • Asynchronous and Synchronous Data Transmission • Rates of Data Transmission • Modes of Data Transmission including Simplex, Half Duplex, and Full Duplex • Bus Properties, Uses, and Types
Module 360 Information Assurance	This module aims to give you a clear understanding of concepts behind information assurance. The learning objectives of this module are that you will be able to explain: • Identity management and Access Control. • The three elements of the CIA triad: Data Integrity, Data Confidentiality and Resource Availability. • The basic operation of event management. 

MODULES AND LEARNING OBJECTIVES

Module	Learning Objectives
Section F: Industrial Control Systems Cybersecurity (Modules 310-370) *continued*	
Module 370 The Security Lifecycle	This module aims to give you a clear understanding of concepts behind the NIST Cyber Security Framework in relation to providing a common language to the Cyber Security lifecycle. The learning objectives of this module are that you will be able to explain: • The NIST Framework key elements- Core, Profile, and Implementation tiers • The five Functions of the NIST Framework • The structure of the Framework core • The most commonly used Informative References of the NIST Framework 

WHAT CURRENT PARTICIPANTS ARE SAYING ABOUT THIS COURSE

"What I am learning at the beginning of the program is really helping me understand the holistic approach of automation, and gain the understanding that it's not just manufacturing, but also analytics, supply chain, and many other aspects of the drug development process. The course so far has been a lot of review for me as an automation person, but it is also very helpful and a good teaching tool for new analysts, giving them an understanding of what automation is."

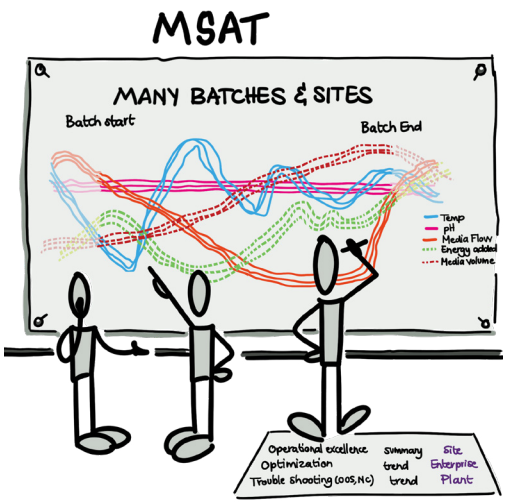
- Rich Smart, Scientist at Biogen

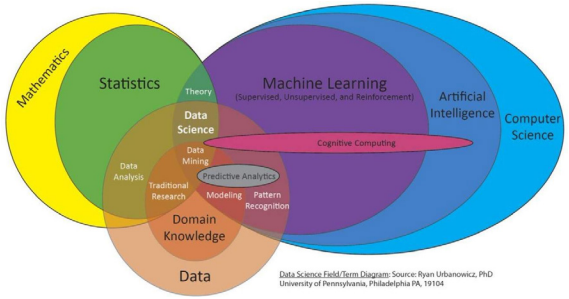
"I personally benefitted greatly from the IAAE learning modules. I actually started working as a contractor with Castle Hill Technologies working on a project in security. Just going through these learning modules over the summer really helped me get up to speed and speak the same language as my boss. Some of the terminology I did not know coming into my work has been taught through these modules."

- Albert Shin, currently pursuing a Master's in Biomanufacturing at NCSU and IAAE® Student Advisory Council Member

COURSE 2: DIGITAL TECHNOLOGY ENABLING DATA ACQUISITION, VISUALIZATION, AND ANALYTICS (3 MODULES, 4 HOURS TOTAL)

This online course consists of three modules as described and illustrated below.

Module	Module Aims	Learning Objectives
400: Data Acquisition (1.5 hours)		
Module 400	**This module aims to introduce you to:** • The main goals and benefits of digital biomanufacturing • What data can a should be captured for biomanufacturing purposes • How data acquisition is foundational for both data analytics and data visualization  	**The learning objectives of this module are that you will be able to:** • Identify key goals of digital biomanufacturing • List the characteristics of big data (the 3 V's plus 2) • Define structured data, unstructured data, and metadata • List the four main steps of digitizing data • Define what main types of data can and should be acquired for biomanufacturing • List key activities of data governance • Explain the meaning of the Industrial Internet of Things (IIoT)

Module	Module Aims	Learning Objectives
410: Data Visualization (1 hour)		
Module 410	This module aims to introduce you to data visualization by helping you: • Start with why, keep it simple, and evaluate at the end • Learn about common data visualization tools available - ranging from business intelligence tools (that require little to no coding), to data science tools (that do require coding skills)	The learning objectives of this module are that you will be able to: • Explain why understanding business objectives, your audience, and insight needs all help you to better communicate data visually • Apply a set of design steps to create a new graph • Critically evaluate any visualization in terms of how informative and emotive it is using a set of criteria
420: Data Analytics (1.5 hours)		
Module 420	This module aims to give you an introduction to data analytics and how to DISCOVER, PREDICT, and PRESENT insights using data analytics tool. Some of the questions that will be asked during this module include: • What are the main types of analytics used to get insights from data? • What is exploratory data analysis? • How is data science different to business intelligence? • What team members will I likely need to work with? • What is the #1 challenge that organizations face regarding analytics? • What are some of the common analytics tools used in biomanufacturing?	The learning objectives of this module are that you will be able to: • Define the three main types of analytics on the analytics spectrum • Explain the purpose of exploratory data analysis • List some analytics platforms/tools and their suitability to discover, predict or report 

WHAT ONE OF OF OUR DEVELOPMENT PARTNERS SAYS ABOUT THIS COURSE

"Collaboration between academics and industry subject matter experts in the Life Sciences led to the design of this course, which introduces students to digital technology concepts in a biomanufacturing setting.

In this course, we cover topics including the initial collection and storage of biomanufacturing process data and its subsequent analysis and transformation into valuable information that is actionable and used to make process and business decisions.

The purpose of this course is to provide students with knowledge and experience, so that they are familiar with the various functions and tools related to data collection and data utilization, which they will encounter in a modern biomanufacturing facility."

- Ryan Barton, Automation/Data Scientist at NCSU BTEC

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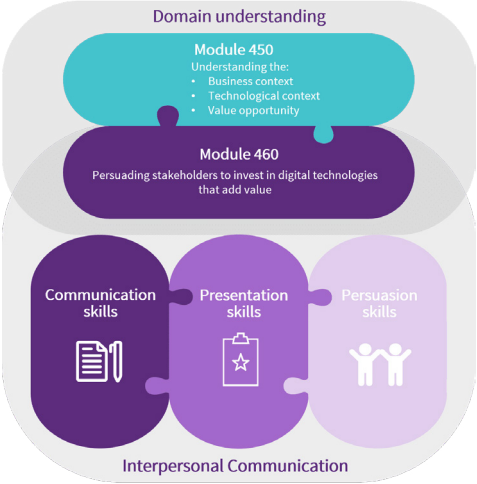
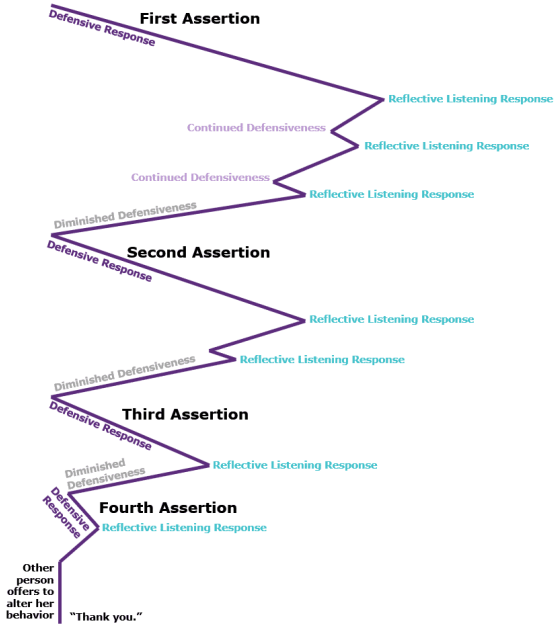
COURSE 3: ADVANCING THE ADOPTION OF DIGITAL TECHNOLOGIES IN THE LIFE SCIENCES (2 MODULES, 2.5 HOURS TOTAL)

This online course consists of two modules as described and illustrated below.

Module	Module Aims	Learning Objectives
450: Framing digital solutions of value within your business and technology context (1.5 hour)		
Module 450	This module aims to explain the importance of understanding both the technological context and business context before you can frame the true value of digital technology solutions for Life Sciences manufacturing. Some of the questions what will be asked and answered in this module include: • What are some ways you can keep pace with advances in technology? • How can you recap the technology context for an audience? • How can you explain a business context in terms of market trends and business drivers? • What does it mean to frame true value of a digital technology solution?	The learning objectives of this module are that you will be able to: • Define your own business context by industry sector and business model • Define your own technological context • Follow steps to better frame the true value of a digital technology solution 

Module	Module Aims	Learning Objectives
460: Persuading stakeholders to invest in digital technologies that add value (1 hour)		
Module 460	Making a presentation that will lead to decisions and actions by your audience requires careful preparation and practice, as well as a delivery that is responsive to the questions from those you are presenting to. This module aims to share with you some of the key preparation and presentation steps used by those who present digital technologies to senior stakeholders. You will also cover some of the skills necessary to persuade others regarding the value of digital technology proposals. Some of the questions that will be asked and answered in this module include: • What should you consider when preparing and presenting digital technology solutions? • What do stakeholders look for in technical presentations? • How can you best address objections or push-back?	The learning objectives of this module are that learners will be able to: • More confidently present the value of digital technology to internal stakeholders • List key steps of planning to present • Explain suitable approaches to respond to objections or push-back 

WHAT ONE OF OUR LIFE SCIENCE ADVISORY BOARD MEMBERS SAYS ABOUT THIS COURSE

"The IAAE online course on Advancing the Adoption of Digital Technologies in the Life Sciences transformed the way I framed my vision of Catalent's digital transformation, and significantly contributed its buy-in by senior management. Joan Mulvihill's way of framing projects particularly resonated. I can tell that within the last couple of months there is increased emphasis at Catalent in terms of the way we view digital technologies, and I'm glad to be playing a part in it. The IAAE education content will undoubtedly play a role in re-skilling and up-skilling our scientists and engineers."

- Chris Demers, Ph.D., Senior Data Scientist, Process Automation, Catalent Biologics

COURSE 4: A PATH TO MODEL BASED BIOMANUFACTURING (6 MODULES, 4 HOURS TOTAL)

This online course consists of six modules as described and illustrated below. For managers and executives we recommend modules 430, 431 and 440 for a big-picture path.

Module	Module Aims	Learning Objectives
430: Demystifying modeling (45 mins)		
Module 430	This module aims to introduce you to models and modeling. You will cover questions such as: • What is a model? • What is the power of models? • What pitfalls should you avoid when using models? • What is the vision of a model-based enterprise?	The learning objectives of this module are that you will be able to: • Describe some of the drivers for modeling • Define key performance indicators that can be improved using models • Explain some of the key pitfalls to avoid when using models • Describe the vision of a model-based enterprise  Modeling as part of your culture schematic

Module	Module Aims	Learning Objectives
431: Digital twins for biomanufacturing (45 mins)		
Module 431	This module aims to introduce you to the concept of digital twins and the different types of digital twins used for biomanufacturing. You will cover questions such as: • What are the benefits of model-based biomanufacturing? • What are the 4Ps of modeling for Life Sciences manufacturing? • What is a digital twin? • What is the difference between a digital model and a digital twin?	The learning objectives of this module are that you will be able to: • Explain key examples of the benefits of model-based biomanufacturing • Describe the 4Ps of biopharmaceutical manufacturing • Describe what a digital twin is • Explain the key differences between a digital model and a digital twin

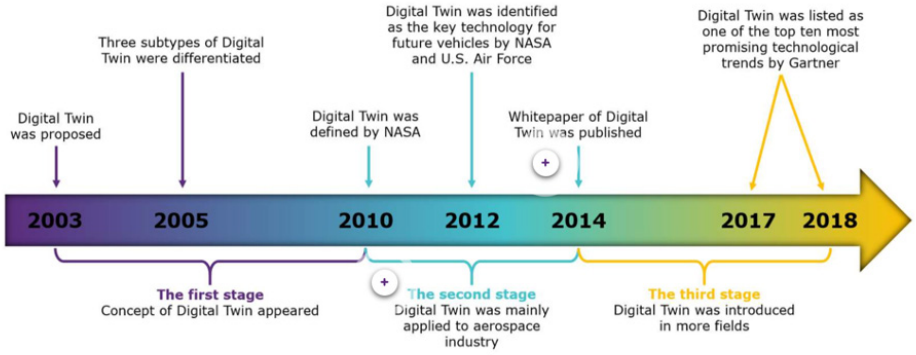
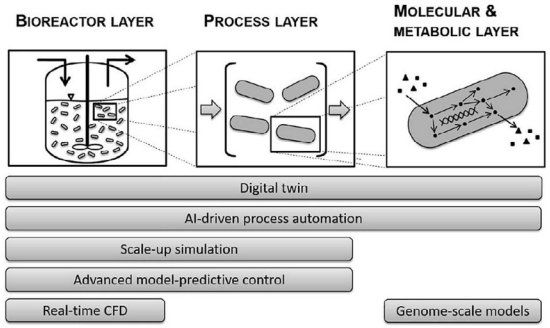


Image Credit: Image recreated based on image from: Digital Twin Driven Smart Manufacturing, Page 5

Module	Module Aims	Learning Objectives
432: Overview of modeling of pharmaceutical processes (45 mins)		
Module 432	This module aims to introduce you in more detail to modeling of pharmaceutical processes. You will cover questions such as: • How can modeling and simulation support Quality by Design workflows? • How does Process Analytical Technology (PAT) rely on modeling? • What are the most common objectives of modeling? • What are some of the different applications of modeling for biomanufacturing? • What are the three main types of modeling approaches? • What do you need to be aware of if your objective changes? • Which models are most suited to batch or continuous processes? • What are typical examples of models used in the biopharmaceutical industry?	The learning objectives of this module are that you will be able to: • Describe different types of models that can be used for different objectives and applications • Explain how Process Analytical Technology relies on modeling • List which type of modeling and which models are suited to various stages of product development of manufacturing (e.g. batch or continuous processes)  (Image Credit: History and Evolution of Modeling in Biotechnology: Modeling & Simulation, Application and Hardware Performance)

Module	Module Aims	Learning Objectives
433: Overview of modeling packages and platforms (30 min)		
Module 433	This module aims to introduce you to some of the packages and platforms used in the Life Sciences industry for model-based biomanufacturing. You will cover questions such as: • What are some of the main statistical and modelling packages used to perform data analysis or create models?	The learning objectives of this module are that you will be able to: • List a number of packages that are used for modeling • Define the manufacturing stage and context models are most suitable for
434: Introduction to a modeling lifecycle framework (30 mins)		
Module 434	This module aims to introduce you to managing models using a lifecycle framework. You will cover questions such as: • Why is model life-cycle management so important? • How are models assessed differently in an industrial context? • What are the main steps in a model lifecycle framework?	The learning objectives of this module are that you will be able to: • Explain why lifecycle management of models is important • Describe the main steps in a model lifecycle framework • Describe a modeling portfolio management process

Module	Module Aims	Learning Objectives
440: Investment considerations for model based biomanufacturing (45 mins)		
Module 440	This module aims to introduce you the factors that impact investment in model-based technologies. You will cover questions such as: • What are the business drivers and economics of model based biomanufacturing? • What are the technology investment considerations? • What are the personnel investment considerations? • What is the future of model-based biomanufacturing?	The learning objectives of this module are that you will be able to: • State key business drivers for model-based biomanufacturing • Outline factors relating to technology investment • Outline personnel investment considerations • Describe the impact on tech transfers of products from one site to another • Explain some of the key equations that support data-driven economic decisions

WHAT SOME OF OUR ACADEMIC PARTNERS SAY ABOUT THIS COURSE

"A path to model based manufacturing is a collection of modules that help explain the modeling concepts which are so frequently mentioned in the biomanufacturing industry. This course not only provides context to how these modeling tools can be utilized, but also delves into the business drivers that should be considered for implementing a modeling culture, as well as the considerations around the management of a modeling project and its lifecycle framework.

This course is beneficial for individuals that are looking for a more fundamental understanding of what is meant by all the buzzwords surrounding modeling, and would like to learn what considerations go into the creation and management of a modeling project.

This course comes at a critical time in the biomanufacturing industry where there is a lot of focus on the digital transformation of manufacturing sites, so that more complete and rich sources of data are available to operators, analysts, and management in order to make critical decisions in a more timely manner. For the industry as a whole to be successful in this transition, there needs to be a better understanding of what is meant by the terminology surrounding modeling, and an understanding of what considerations need to be made before embarking on this journey towards a modeling culture."

- Ryan Barton, Ph.D., Automation/Data Scientist at NC State BTEC

"The IAAE online course called A path to model-based biomanufacturing introduces this complex and important field in very understandable manner. It helps faculty like me to see where the industry is headed, and, encourage students to think along these lines of gaining data analysis and modeling skills. It is great for faculty professional development in computer science, engineering, and biotech for both four-year as well as other community college programs."

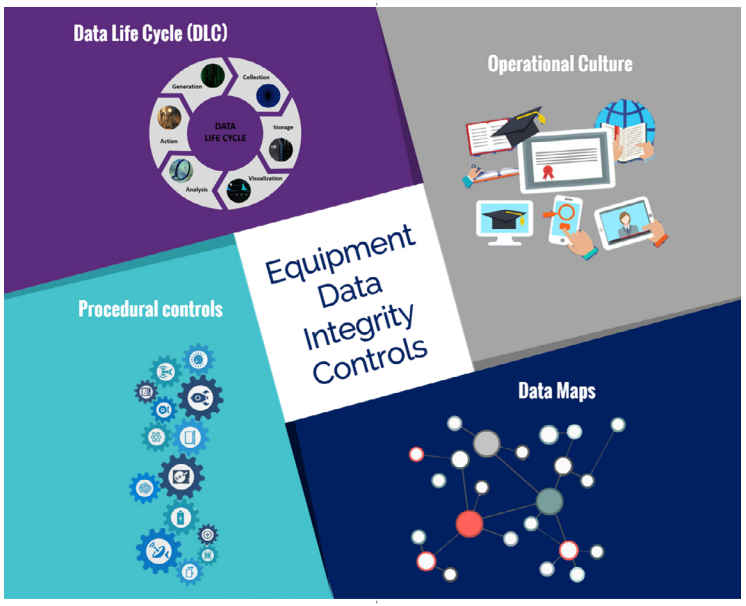
- Savita Prabhakar, Assistant Professor and Program Manager Biotechnology at Frederick Community College, MD, USA

COURSE 5: ELECTRONIC DATA INTEGRITY FOR LIFE SCIENCES MANUFACTURING (4 MODULES, 4 HOURS TOTAL)

This online course consists of four modules as described and illustrated below.

Module	Module Aims	Learning Objectives
500: Electronic data integrity in the Life Sciences industry (1 hour)		
Module 500	This module aims to: 1. Give you an introduction into Data Integrity in industry 2. Introduce you to the Data Life Cycle 3. Introduce you to the importance of appropriate corporate culture	The learning objectives for this module will allow you to: 1. Define 'What is Data Integrity?' 2. Explain ALCOA+ 3. Explain the Data Life Cycle 
510: Computer system validation (1 hour)		
Module 510	This module aims to: 1. Introduce you to system validation and its importance 2. Give you an introduction into Data Governance 3. Introduce you to IT systems and the risks and control measures associated with such systems	The learning objectives of this module are that you will be able to: 1. Explain what is validation and why it's important to a company 2. Describe what is data governance 3. Explain the components and risks of an IT system

Module	Module Aims	Learning Objectives
520: Equipment considerations for data integrity (1 hour)		
Module 520	This module aims to: 1. Give you an introduction to the types of equipment in the life sciences industry 2. Introduce you to the risks associated with equipment data 3. Introduce you to some equipment best practices	The learning objectives for this module will allow you to: 1. Explain the different types of equipment 2. Explain the risks associated with equipment data 3. Describe the control measures that can be undertaken to mitigate data risks



Module	Module Aims	Learning Objectives
Module 530: Application Types for Data Integrity (1 hour)		
Module 530	This module aims to: 1. Introduce you to the different application types in industry 2. Introduce you to the risks associated with each system application 3. Impart on you the controls and best practices used to mitigate these risks	The learning objectives of this module are that you will be able to: 1. Explain what an Enterprise/Local system application is 2. Describe the risks associated with an Enterprise/Local system 3. Describe the appropriate actions undertaken to mitigate inherent risks

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CLOSING SUMMARY PAGE

The IAAE® courses described in this catalog have been reviewed or are currently under review by SMEs at Merck and Genentech. We have received positive feedback from senior stakeholders, industry professionals, professors, and students across the U.S. and globally.

"The wide breadth of content offered by the IAAE® yields an opportunity to increase capability across a commensurately diverse set of functional groups and raise the tide for all boats."

- Dan Kim, Director, Automation & Digital Operations, PSC Biopharmaceuticals with GSK