

Continuum™ CFR Compliance Pack™

Life Sciences Solutions



CFR Compliance Pack Benefits:

- Provides alarm notification for any out-of-specification conditions
- Integrates security/card access control
- Monitors and records the values of critical variables
- Records and reports activities of all personnel
- Extends compliance to all devices and subsystems

Plus, get all the advantages of electronic record-keeping, such as fast information exchange and data mining for manufacturing management.

Know and Record Everything Critical About Your Regulated Facility



The FDA is stepping up regulatory enforcement. Is your facility audit-ready? If not, you face possible Notices of Inspectional Observations (483s), Warning Letters — even substantial fines and plant shutdowns!

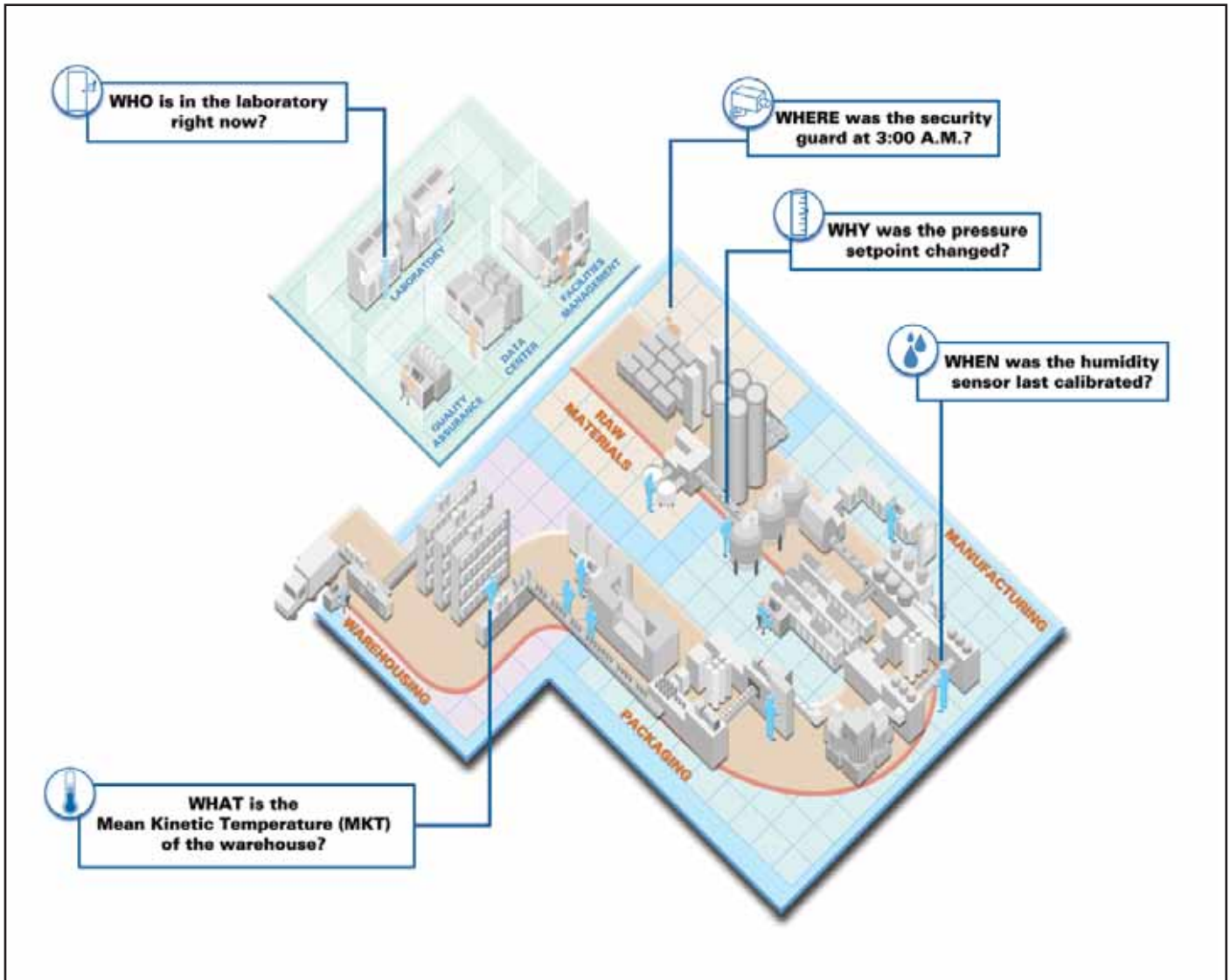
Achieving compliance is no small task! Its scope extends beyond a company's environmental and production control systems and operating procedures — into virtually every area of the plant and across entire regulated industry supply chains. Today's Biotech, Pharmaceutical, and other FDA-regulated industries are quickly realizing the importance of 21 CFR Part 11 compliance.

They're viewing Part 11 not as a burden, but as an opportunity to improve their manufacturing process and their entire business. By moving to a fully "paperless" environment, companies can reduce costs, accelerate time-to-market, and ensure a higher degree of quality and consistency in their products. As a result, these companies gain a powerful competitive advantage.

THE TAC® SOLUTION

Founded in 1925, TAC has become a leading manufacturer of facility automation systems for the Biotech and Pharmaceutical markets. Our flagship product, the Continuum Facility Management System, provides HVAC control, security alarm monitoring, access control, badging, video surveillance, and environmental monitoring for regulated facilities worldwide.

Today TAC has taken this leadership role a step further to help FDA-regulated businesses comply with 21 CFR Part 11. Introducing CFR Compliance Pack. This enhancement to our Continuum software provides facility-wide accountability and traceability of both the environmental and security conditions that can impact the quality and safety of the end product.



TOTAL ENVIRONMENT MANAGEMENT UNDER ONE UMBRELLA

CFR Compliance Pack delivers a “Total Environment Management” solution. Using detailed audit trails and enforced operator responses, CFR Compliance Pack ensures that all process-related environmental conditions are monitored and all access events and security alarms are recorded within a common regulatory compliance-ready architecture. A temperature set point change, the addition of an improper ingredient, a change in relative humidity, a variation in ultraviolet light

levels or, just as importantly, unauthorized access to a lab area or computer system — CFR Compliance Pack answers the who?, what?, when?, where?, and why? for these events.

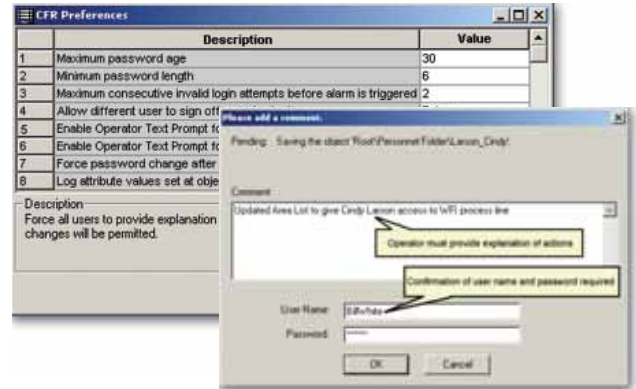
How? CFR Compliance Pack maintains a complete archive of all system events, consolidated into one reporting structure for effortless search and retrieval. It’s information you need (and the FDA requires) to ensure the environmental integrity of your total manufacturing product life cycle.



When it comes to regulatory compliance, we have you covered . . .

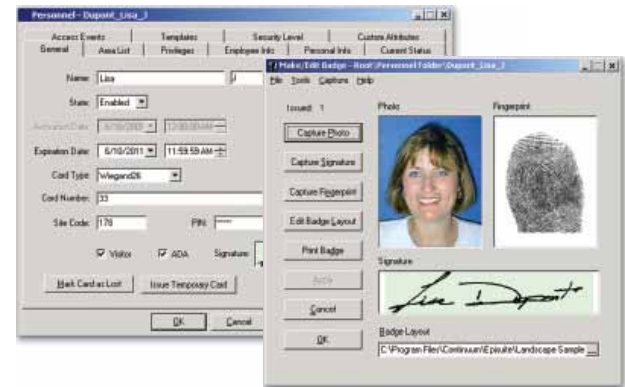
EASY SET UP AND OPERATION

- Password expiration, minimum length, and confidentiality enforcement
- User-specific inactivity time-out periods
- Trigger alarms on selectable number of invalid user login attempts and attempted login by “disabled” users
- Globally enable sign-off and operator explanation of all system changes and alarm acknowledgments
- Operators must provide an electronically signed explanation of their actions



COMPREHENSIVE PERSONNEL INFORMATION MANAGEMENT

- Groups/individuals can be granted or denied access to particular facility areas, e.g., GxP/Non-GxP
- Consolidation of multiple biometric and other identity authentication data sources
- Import/export data from popular HR database applications such as PeopleSoft, SAP, Oracle, Kronos, etc.
- Employee access card and badge creation/management features



TAILORED SECURITY LEVELS

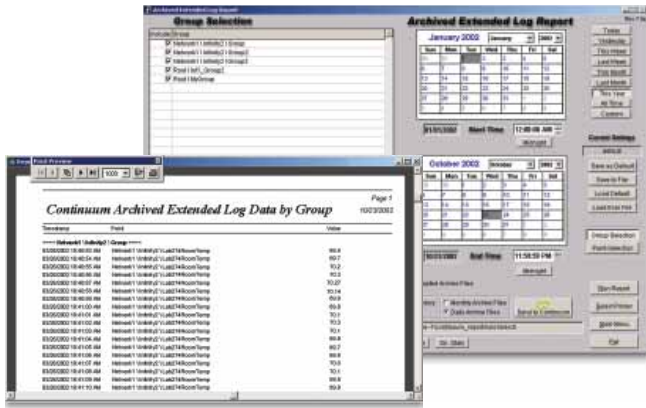
- Highly configurable and granular security model
- System can be logically partitioned to ensure only authorized individuals have access to particular system resources – networks, controllers, I/O points, programs, graphics, etc.



DETAILED AUDIT TRAILS

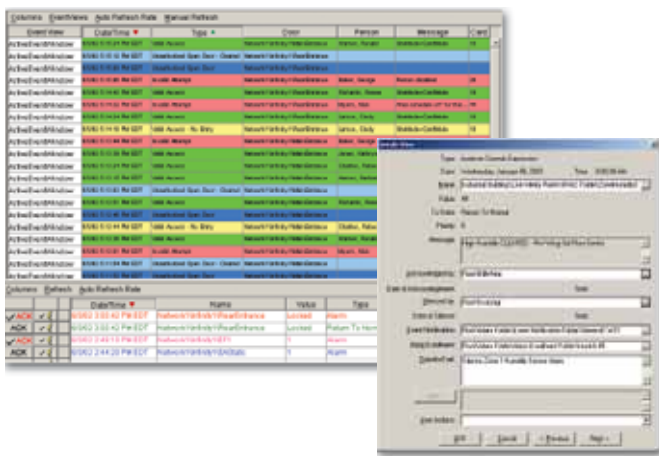
- Electronic records of every operator action electronically signed with explanatory text and securely logged to central database
- Full accountability and traceability supported by automatic capture of who?, what?, when?, where?, and why? - related information
- Multiple customizable views — sort and filter by date/time, operator, facility area, device, workstation, etc.
- Print and export to HTML, CSV, or PDF file formats





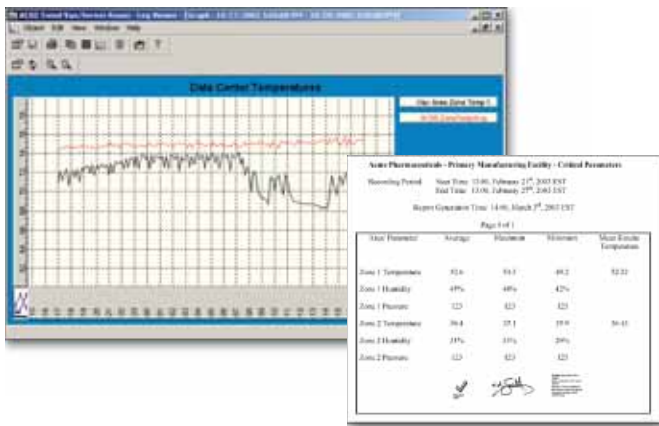
SECURE DATA LOGGING AND ARCHIVING

- All critical parameters are logged both locally in field controllers and in a central database
- Automatic record reconciliation after communication disruptions
- All logged data is automatically backed-up to a secure, separate encrypted database archive
- Easy textual and graphical display of any live, centrally logged, or archived database values



ADVANCED ALARM MANAGEMENT

- Highly customizable user interface for consolidated management of environmental and security alarm conditions
- Supports sophisticated alarm prioritization and notification policies
- Forward alarms to email addresses, pagers, and printers
- Alarms can trigger the automatic display of a particular graphical display, and generate reports and unique voice message audio alerts



FLEXIBLE REPORTING OPTIONS

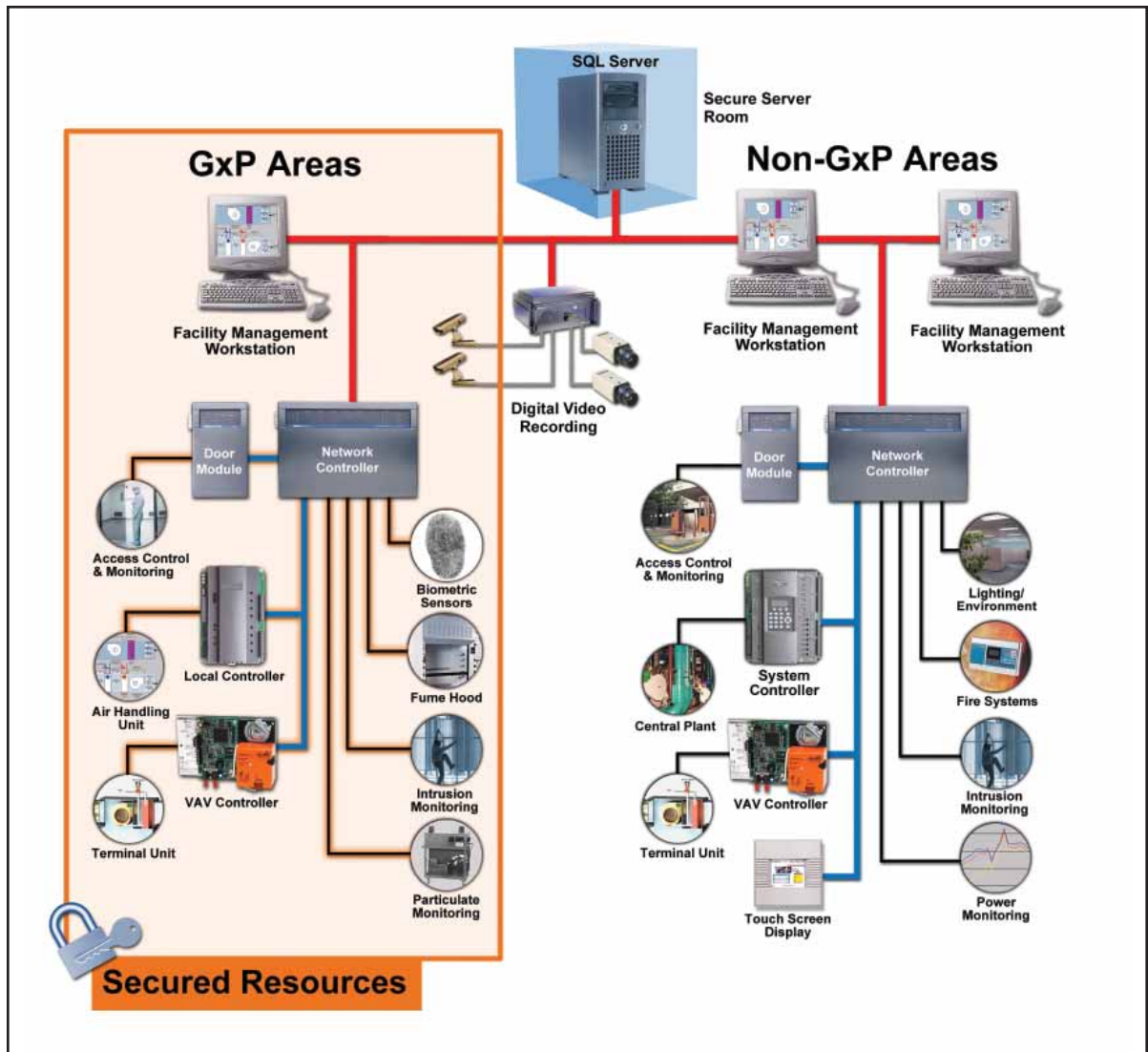
- Multiple preconfigured or user-definable report formats
- Dynamically apply qualifiers to filter or highlight records based on any attribute criteria
- Write reports to PDF files and apply Digital Signatures with Adobe Acrobat
- Generate custom report formats using HTML templates –view in any browser



IT RESOURCE PROTECTION

- Utilize Continuum NetController's native, plug & play, support of SNMP to allow monitoring and protection of the IT infrastructure environment
- Discover and map Continuum NetControllers with popular Network Management System (NMS) tools such as HP OpenView, CA Unicenter, CiscoWorks, IBM/Tivoli Netview, etc.

Regulated/Non-Regulated Partitioned Architecture



ONE SYSTEM COVERS YOUR WHOLE FACILITY!

A single Continuum system can control both GxP and Non-GxP facility areas.

With strict user authentication, the Continuum system ensures only authorized individuals have access to particular system resources

QUALITY PRODUCTS MANUFACTURED TO THE HIGHEST STANDARDS

TAC has built a solid reputation based on quality and reliability. All products are designed, built, and 100% unit tested on site at our North Andover, Massachusetts headquarters. In addition, our entire facility undergoes frequent vendor audits, including our quality system, development life cycle methodology, and change control and configuration management procedures.



COMPREHENSIVE TRAINING DESIGNED WITH OUR CUSTOMERS' NEEDS IN MIND

TAC provides hands-on classroom training at our Corporate Headquarters in North Andover, Massachusetts, at our regional offices, and at customer sites worldwide.

We offer a broad range of courses to meet the diverse requirements of TAC Representatives and our customers. In addition, regulated industry customers can be assured that their TAC System Integrator has undergone advanced training in CFR Compliance Pack implementation.



EXPERIENCED INSTALLATION AND SUPPORT SERVICES

TAC systems are installed worldwide through a network of over 400 factory-certified Automation Representatives in 40 countries. These Representatives are highly trained, experienced system integrators who provide full turn-key solutions, along with the quality local service and support you expect today . . . and in the future.

TAC's System Integration Services (SIS) group is also available to provide full turn-key solutions. SIS specializes in mission critical applications, including laboratories, pharmaceutical production suites, and validation services. Utilizing branch offices in Massachusetts, New Jersey, Pennsylvania, Rhode Island, Puerto Rico, and Singapore, SIS can mobilize a core team of pharmaceutical industry experts and staff projects with local resources.



Our FDA-regulated industry

customers include:

AstraZeneca
Abbott Laboratories
Amgen
Aventis
Boots
Colgate-Palmolive
Eli Lilly
Ethicon
GlaxoSmithKline
Johnson & Johnson
Merck
Novartis
Pharmacia
Pfizer
Schering-Plough
Wyeth

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