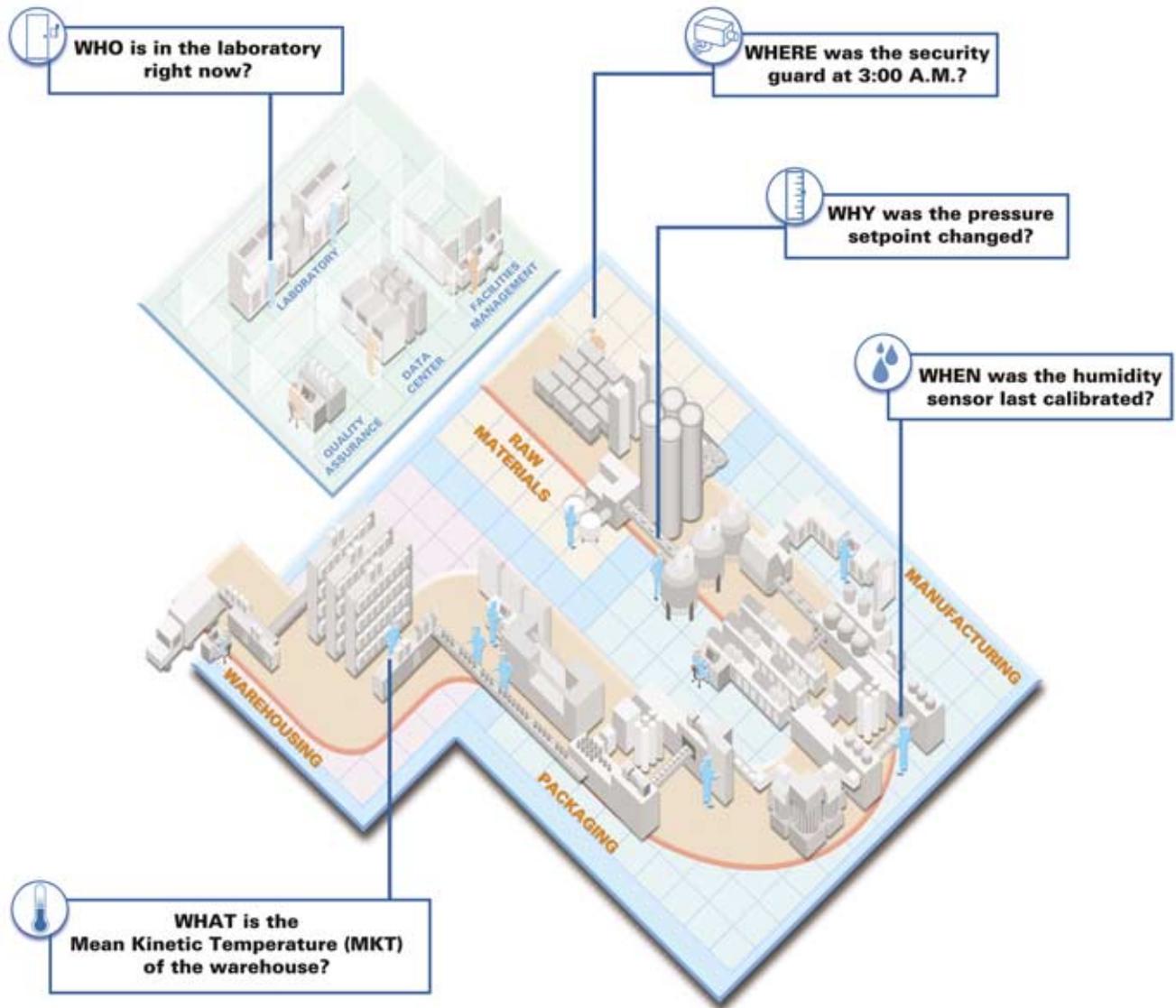


Know and Record Everything About Your Regulated Facility



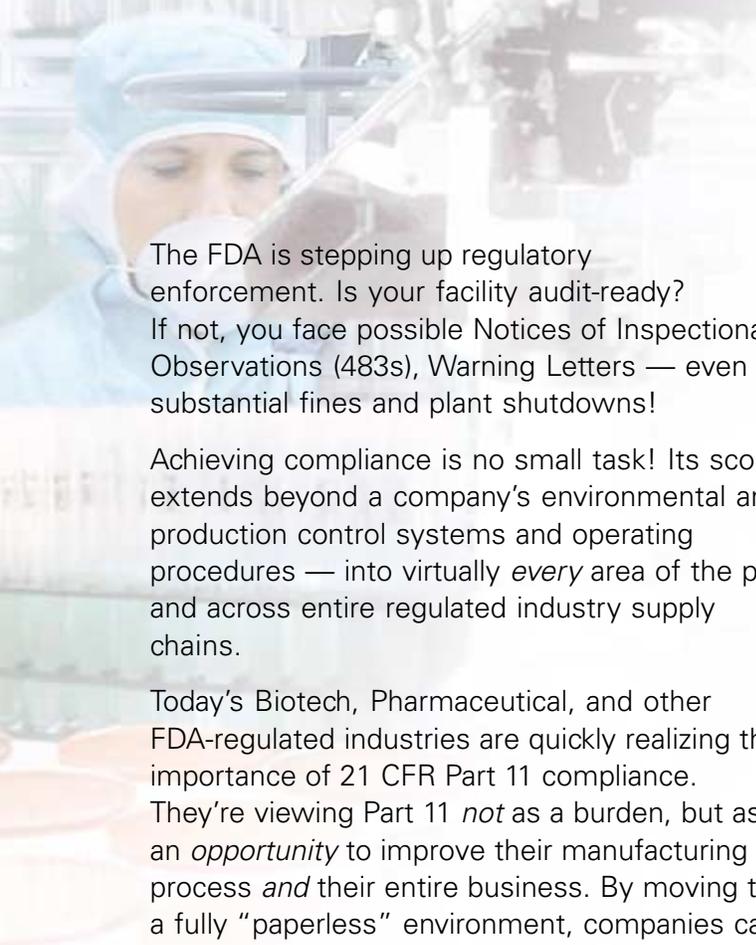
How?

Continuum®



COMPLIANCE PACK™

Delivering Total Environment Management

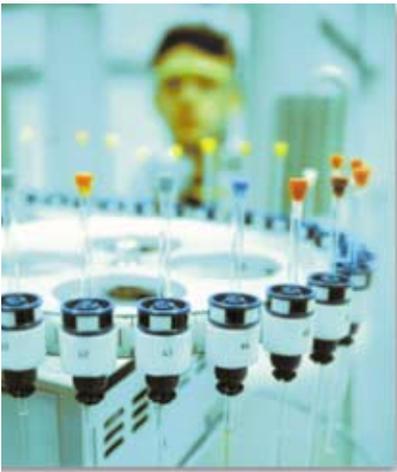


The FDA is stepping up regulatory enforcement. Is your facility audit-ready? If not, you face possible Notices of Inspectional Observations (483s), Warning Letters — even substantial fines and plant shutdowns!

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 Andover Solution

Founded in 1975, Andover Controls 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 Andover 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.

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.



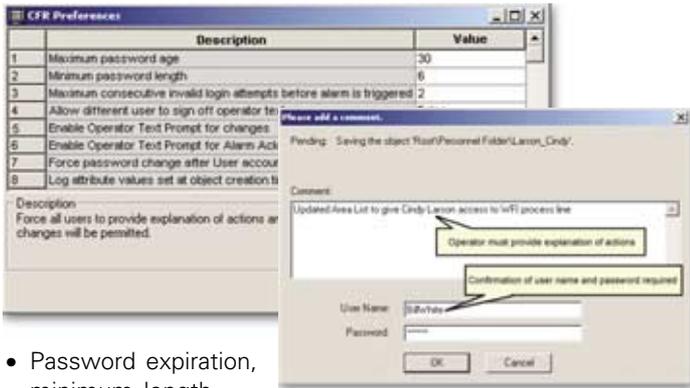
Total Environment Management Under One Umbrella

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.

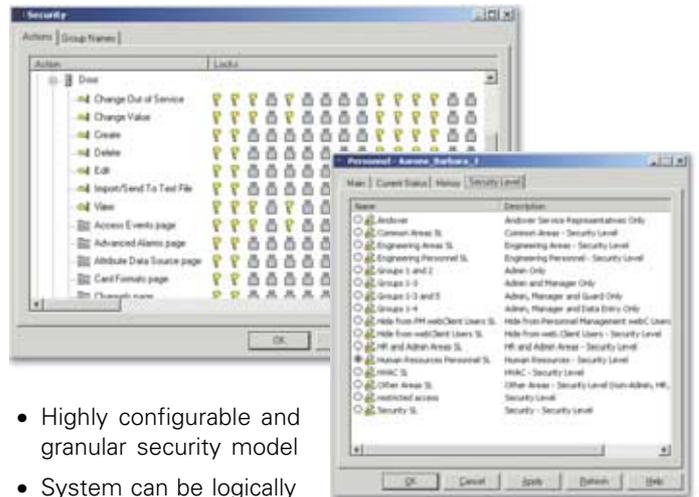
When it comes to regulatory compliance,

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

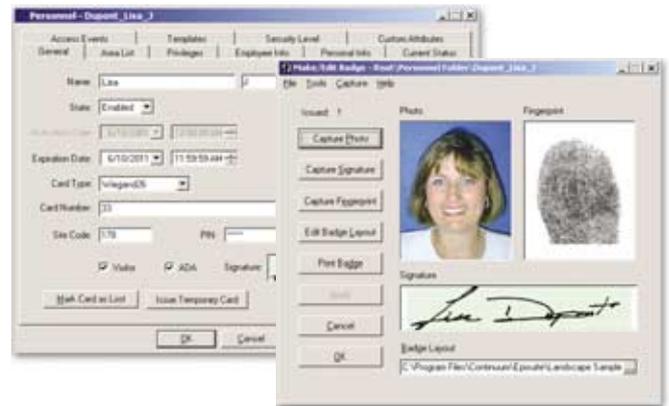
Tailored Security Levels



- 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.

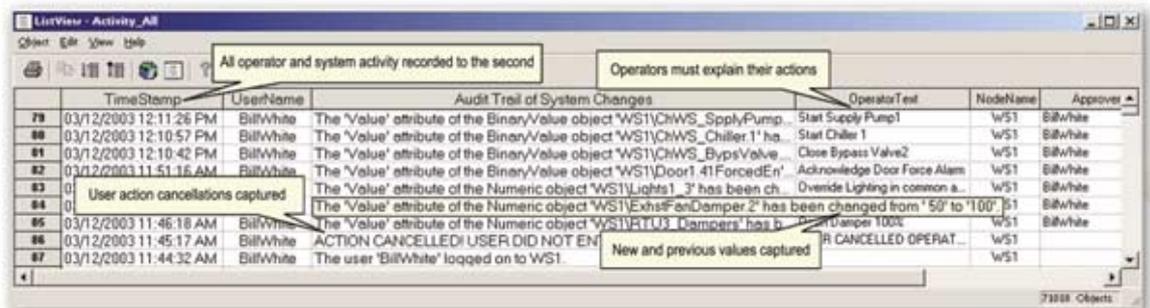
Comprehensive Personnel Information Management

- 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



Detailed Audit Trails

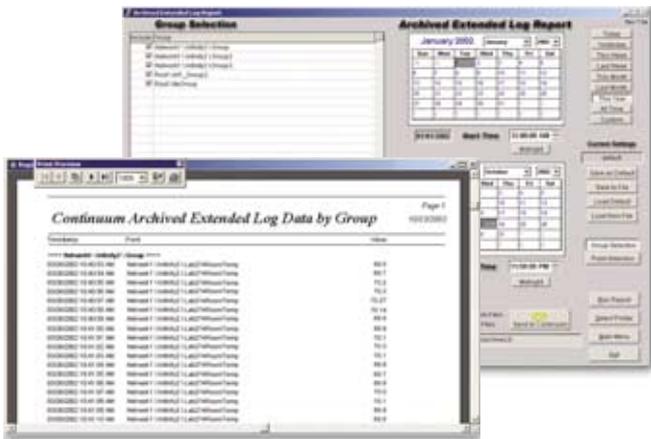
- Electronic records of every operator action electronically signed with explanatory text and securely logged to central database
- Full accountability and traceability supported by automatic capture of who?, what?, when?, where?, and why? - related information



- 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

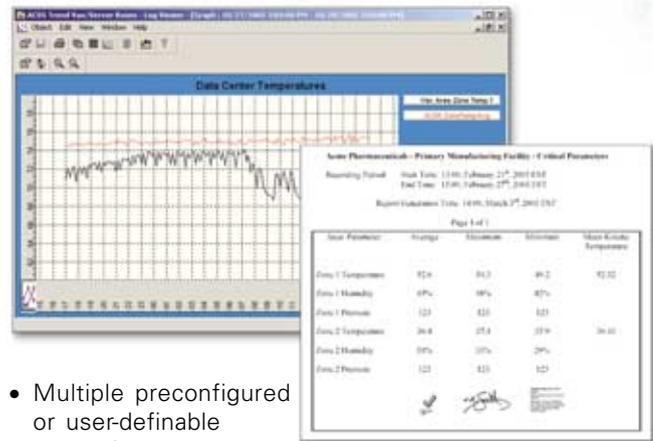
we have you covered . . .

Secure Data Logging and Archiving



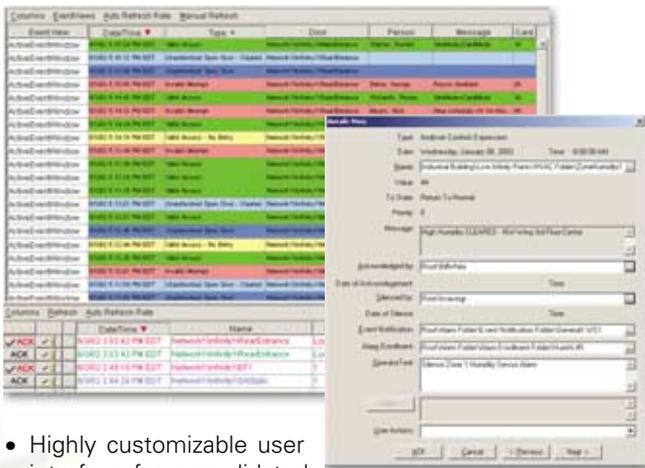
- All critical parameters are logged both locally in field controllers and in a central database
- Automatic record reconciliation after communication disruptions
- All logged data is automatically backed-up to a secure, separate encrypted database archive
- Easy textual and graphical display of any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

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

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

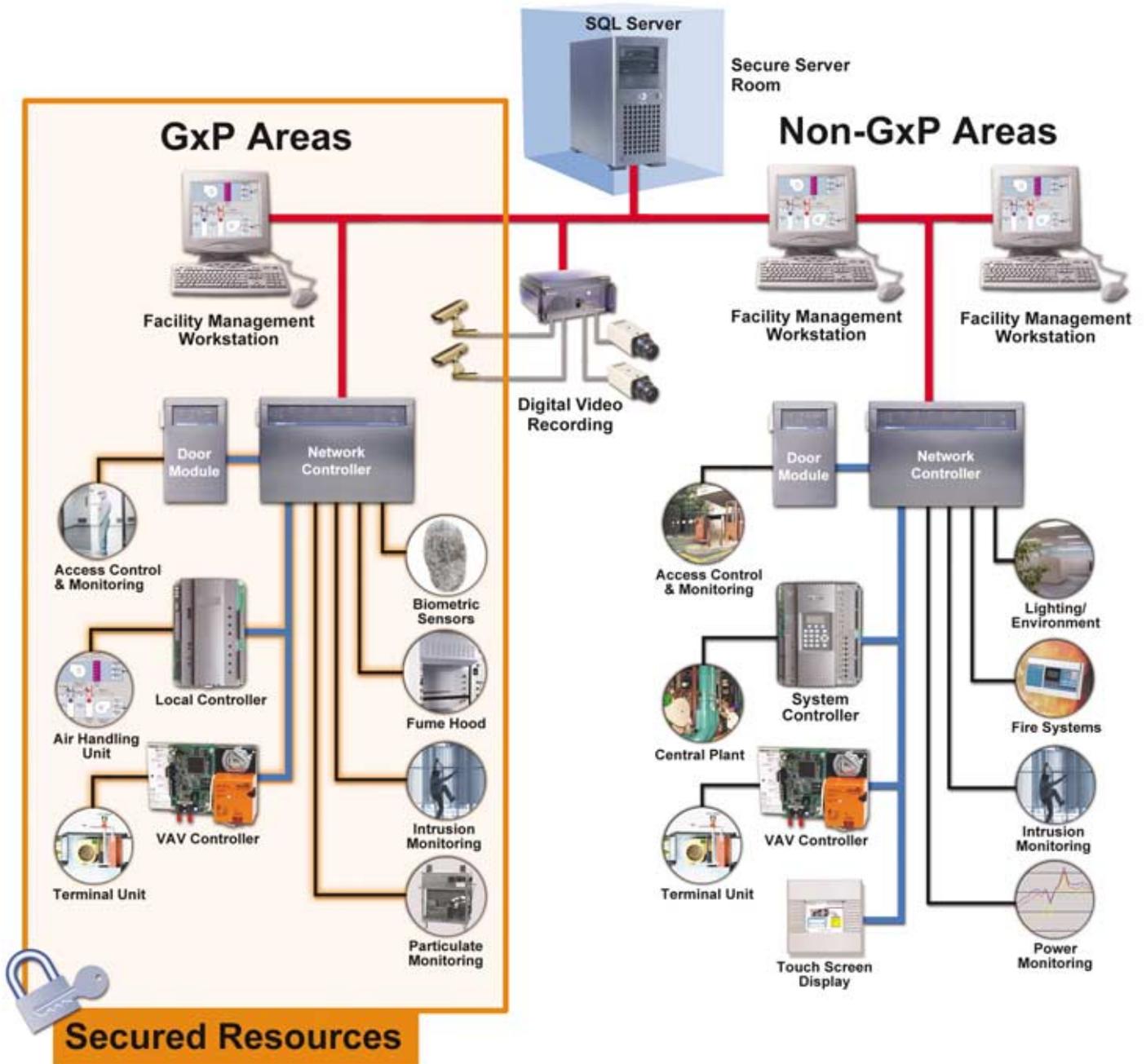
IT Resource Protection



- 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

Andover Controls has built a solid reputation based on quality and reliability. All products are designed, built, and 100% unit tested on site at our 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

Andover Controls provides hands-on classroom training at our Corporate Headquarters in Andover, Massachusetts, at our regional offices, and at customer sites worldwide. We offer a broad range of courses to meet the diverse requirements of Andover Representatives and our customers.

In addition, regulated industry customers can be assured that their Andover Controls System Integrator has undergone advanced training in CFR Compliance Pack™ implementation.

Experienced Installation and Support Services

Andover 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.

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

Andover Controls Corp. World Headquarters

300 Brickstone Square
Andover, Massachusetts
01810 USA
Tel: +1 978 470 0555
Fax: +1 978 470 0946

Andover Controls Ltd. Europe

Smisby Road
Ashby-de-la-Zouch
Leicestershire LE65 2UG
England
Tel: +44 1530 417733
Fax: +44 1530 415436

Andover Controls Germany

Am Seerhein 8
D-78467 Konstanz
Germany
Tel: +49 7531 99370
Fax: +49 7531 993710

Andover Controls France

Immeuble Dolomites 2
58 Rue Roger Salengro
94126 Fontenay Sous
Bois Cedex, France
Tel: +33 1 53 99 16 16
Fax: +33 1 53 99 16 15

Andover Controls Poland

Radzikowskiego 56
31-315 Krakow
Poland
Tel: +48 126385500
Fax: +48 126385500

Andover Controls Asia

Unit 1201-02, Phase 1,
Cheuk Nang Centre
9 Hillwood Road,
Tsim Sha Tsui East
Kowloon, Hong Kong
Tel: +852 2739 5497
Fax: +852 2739 7350

Andover Controls Latin America

Insurgentes 1722-501
Col. Florida
Mexico D.F. 01030,
Mexico
Tel: +52 55 5661 5672
Fax: +52 55 5661 5415

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