

# APOGEE Compliance Solution

For FDA-Regulated Facilities

Building Technologies

**SIEMENS**



## Turn compliance into a competitive advantage

Siemens combines innovative technology and professional services to create the best total solution for compliance.

The APOGEE® Compliance Solution for FDA-Regulated Facilities not only provides a traceable, secure and reliable facility information management system — it helps you minimize operating costs, increase productivity and get to market faster.

Combining innovative technology with professional services, we help you every step of the way with consulting, training, compliance analysis services and engineering support.

The APOGEE Compliance Solution gives you end-to-end monitoring and control over facility conditions and data in your manufacturing operation, including data security, electronic signatures, audit trails, record/signature linking, system/device checks, ease of validation and integration with third-party systems. This ensures that your facility meets cGMP requirements as well as current regulations governing electronic records and signatures.



## The APOGEE Compliance Solution delivers tangible ROI benefits:

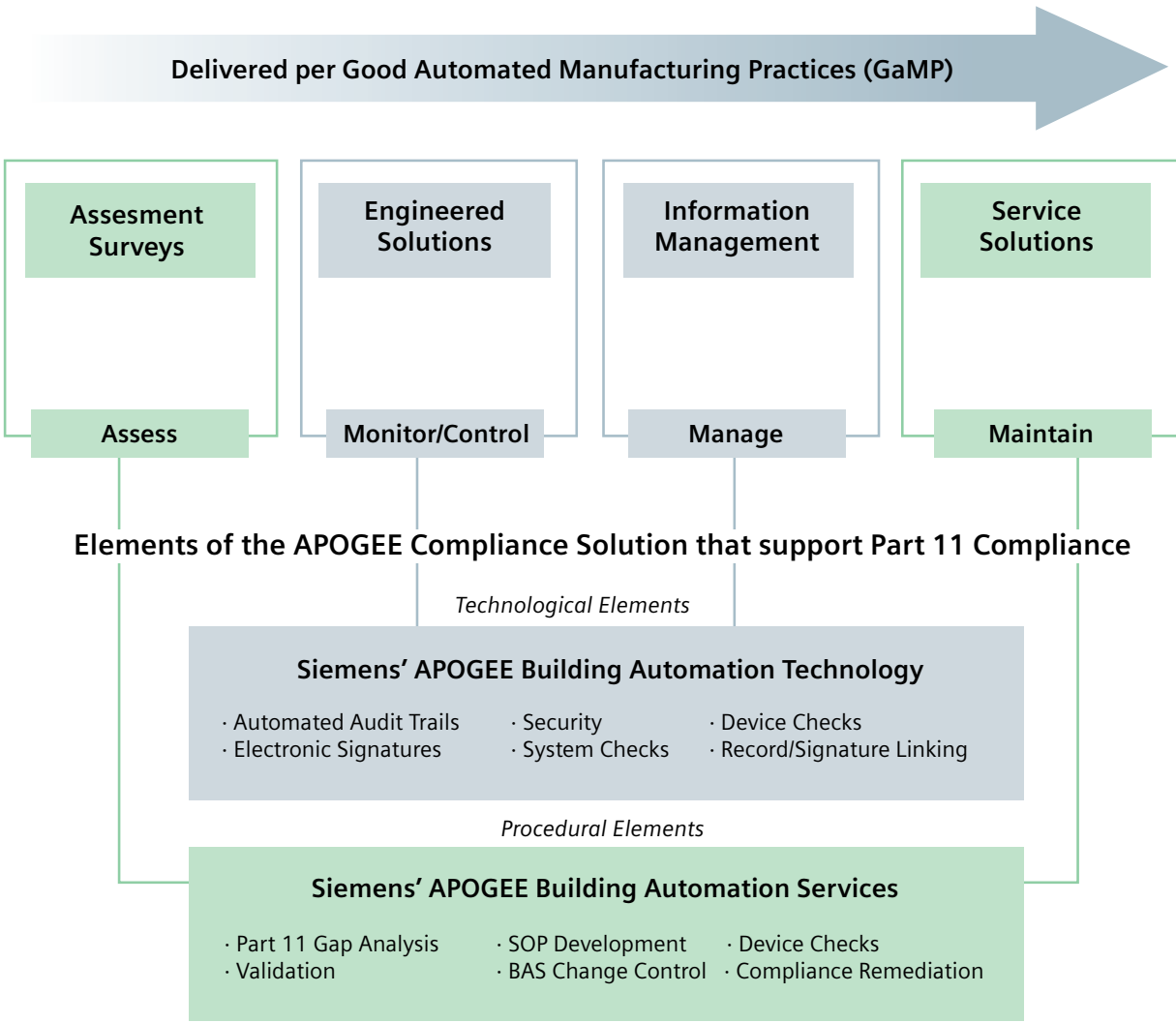
- Meet the electronic records and signatures requirements of 21 CFR Part 11 and maintain a traceable, reliable and secure information management system.
- Meet 21 CFR Parts 210/211 (cGMP) requirements as applied to the Building Automation System.
- Establish a basis for a life cycle approach per GaMP guidelines.
- Ensure the quality of environmental conditions in critical areas.
- Provide a safe and healthy work environment to minimize risk and liability.
- Improve staff productivity by developing a turn-key operation through integration of third-party systems and components.
- Minimize operational costs through monitoring and control of environmental, equipment and utility conditions.
- Provide a secure environment to protect staff, research integrity, product and processes.



# The APOGEE Compliance Solution for FDA-Regulated Facilities

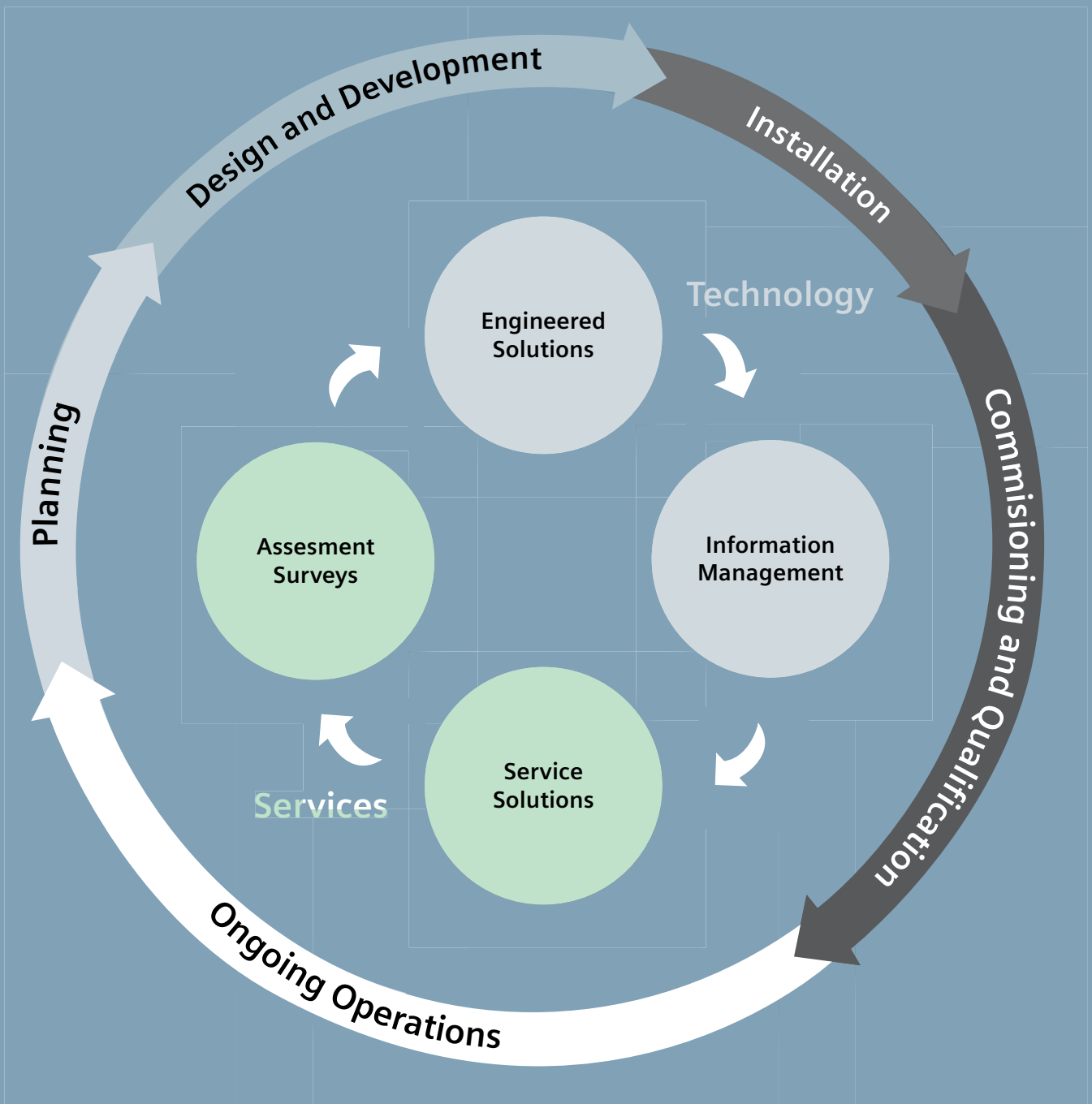
Structured around the APOGEE Building Automation System, our bundled compliance solution enables you to electronically capture building operation and environmental condition records — and their associated signatures — in a secure format to achieve and maintain compliance with 21 CFR Part 11.

Unlike competitive systems, the Siemens solution was designed to operate with its APOGEE Building Automation System from the ground up. So you get a completely integrated solution, supported and serviced by a single reliable source.



The APOGEE Compliance Solution provides a complete life cycle approach to facility automation and compliance that includes a full array of technology and services solutions.

# A complete facility life cycle solution



# Technology

## Meeting the Technological Elements of Compliance

### Engineered solutions

#### Building automation for centralized facility management and control

At the core of our compliance solution is the APOGEE Building Automation System, a sophisticated building automation solution that provides comprehensive monitoring and control capabilities for critical facility conditions.

The APOGEE Building Automation System supports regulatory compliance by ensuring the integrity of electronic records throughout their entire life cycle – from the point of creation to the end of a record's useful life.

With its advanced architecture, the APOGEE Building Automation System also enables integration with third-party BAS components and software through BACnet®, Modbus®, LonWorks®, OPC®, or custom drivers and interfaces.

This means you can monitor, control and document all facility subsystems and devices from a single workstation while maintaining full regulatory compliance. This level of integration helps boost efficiency, lowers cost and reduces risks in your facility.

- BUILDING AUTOMATION AND HVAC CONTROLS
- SECURITY
- INTEGRATION OF CRITICAL SYSTEMS AND DEVICES
- ALARMING/ ALARM ESCALATION
- REMOTE NOTIFICATION
- WEB-BASED ACCESS



### Information management

#### Powerful, intuitive access to facility control data

The APOGEE Building Automation System provides simple, centralized access to facility system information through its Insight® workstations. Facility managers, engineers, production managers, scientists and quality control professionals can all access, view and share information generated by the APOGEE Building Automation System.

With the InfoCenter Suite® archiving and reporting software, you can retrieve and manage voluminous amounts of historical data generated by new or existing control and management systems – from a single building or an entire campus – and generate reports for long-term data analysis.

The InfoCenter Suite solution also provides electronic signatures — digital representations used to authorize or "sign" electronic reports. This means your entire compliance process can be electronic with little or no need for paper-based documents.

- REAL-TIME MONITORING
- ALARM INFORMATION MANAGEMENT
- DATA TRENDING
- DATA ARCHIVING
- REPORTING
- WEB-BASED ACCESS



# Services

## Meeting the Procedural Elements of Compliance

### Assessment surveys

**Understanding where you are now**

To help you understand the current conditions of your facility's systems and develop a plan to address your needs, Siemens provides assessment surveys. An assessment survey analyzes the critical functions of your manufacturing facility to identify potential regulatory and efficiency issues.

Our interdisciplinary team identifies those processes that are currently successful as well as areas in need of improvement and targets solutions for maximum benefit.

These comprehensive assessments not only provide you with a thorough gap analysis or benchmark, but also form the basis for developing a strategic plan that will guide you in achieving your facility performance goals.

### Service solutions

**Maintaining the established state of control**

We can ensure your day-to-day operations are maintained to established standards on a 24/7 basis. With over 100 field offices across North America, our local service technicians are highly experienced and easily accessible to provide quality service when you need it.

Siemens Building Technologies offers a full complement of services including Customer Support, Compliance Services, Facility Information Services and a wide range of Technical Support Services to keep your systems up and running now and in the future.

- **BAS PART 11 COMPLIANCE: GAP ANALYSIS**
- **BAS VALIDATION: CRITICAL SYSTEM AND COMPONENT IMPACT ASSESSMENT**

- **CUSTOMER SUPPORT SERVICES**
- **FACILITY INFORMATION SERVICES**
- **COMPLIANCE SERVICES**
- **TECHNICAL SERVICES**
- **PERFORMANCE UPDATES**



#### **Customer support services**

Education services  
Application & technology consulting  
Operator coaching  
Onsite building performance specialist

#### **Facility information services**

Environmental reporting and consulting  
InfoCenter Suite custom report design and creation  
InfoCenter Suite system administration  
InfoCenter Suite user training  
Data Migration

#### **Technical support services**

Automation controls analysis and optimization  
Business protection and recovery services  
Control loop analysis and optimization  
Repair and replacement services  
Emergency onsite response  
Emergency online response  
Network analysis and optimization  
Remote facility monitoring

#### **Compliance support services**

Regulatory training  
Safety training  
Consultative services for BAS  
regulatory compliance  
Specification writing  
SOP writing  
Validation  
Change control for system updates  
Factory acceptance tests (FAT)  
High-level commissioning  
GMP remediation  
Engineering support  
Chemical fume hood testing  
Bio-safety cabinet certification  
Re-entrainment testing  
Room pressurization testing

#### **System performance updates**

Field panel updates  
Firmware updates  
Software updates  
Datamate Advanced software

- BUILDING AUTOMATION
- HVAC CONTROLS
- SYSTEMS INTEGRATION
- FIRE ALARM AND LIFE SAFETY
- SECURITY
- LABORATORY SOLUTIONS
- INDOOR AIR QUALITY
- ENERGY SERVICES AND SOLUTIONS
- MECHANICAL SYSTEMS SERVICES
- PERFORMANCE-BASED SOLUTIONS
- FACILITY MANAGEMENT SERVICES



## Siemens expertise is unmatched

### We understand your facility compliance needs

Our expertise in critical manufacturing operations has been proven throughout North America. We provide a comprehensive building solutions program for design, installation, qualification and maintenance of buildings with or without cGMP requirements.

We're committed to the long-term success of your compliance solutions. To this end, we have established a dedicated regulatory compliance team. These specialists oversee development of our compliance efforts and guide and support our field organization in the application of regulatory compliance solutions.

Ongoing support services ensure that your system continues to meet regulatory requirements and achieves operational efficiency targets. Our compliance teams are an integrated part of the Siemens Building Technologies organization. So when you need service and support, you simply call one reliable source — not two or three different vendors.

Contact Siemens Building Technologies today and find out how we can help you achieve compliance at your facility.

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