



PROPHARMA  
GROUP

*Experience | Integrity | Commitment*

Life Sciences





ProPharma Group is an industry leader providing qualification, compliance and technical services to the pharmaceutical, biotechnology and medical device industries. **We focus on enabling our customers to improve their operations, revitalize their facilities, and maintain quality leadership in a challenging and changing regulatory environment.** We understand that our clients are driven by aggressive timelines and are comfortable working in such an environment while maintaining a strong integrity and commitment to compliance.

**ProPharma Group is built on the foundation of developing long-term relationships with clients.** With this in mind, each project starts with a client kickoff meeting to correctly understand the project goals, timelines and limitations. Together we develop a project plan and determine the critical factors for success.



focus foundation



expertise challenges



We assemble our project teams to best meet the needs of the client. Each project manager has a combination of project management and project-related technical abilities to successfully lead a cross-functional team. **The broad array of our technical expertise, our institutional knowledge base, and the size of our consulting staff ensures that each project has the best possible team.**

Our compliance, validation and scientific professionals have expertise in biology, chemistry, engineering, information technology, manufacturing, project management, quality assurance and quality control. **The majority of our staff's experience comes from working directly for operating companies, so they understand the unique concerns and challenges that are faced in a regulated environment.** We attract talented people to our organization by offering competitive benefit packages and creating an atmosphere that fosters a long term relationship between our colleagues and our clients. This long term perspective guides us day-to-day to make the right decisions for both our clients and colleagues.



our services

# Commissioning & Qualification

## Commissioning Services

Commissioning is a well planned, documented and managed approach to the start-up and turnover of facilities, systems and equipment to the end-user. This results in an operational, safe, and functional system that meets established design requirements and end-user quality expectations.

Following current industry standards, such as ASTM E2500 and those from ISPE, ProPharma Group can provide commissioning documents that verify proper installation, operation at start-up, functional performance, and turnover of facilities, systems and equipment. Our commissioning services include:

- Developing and executing commissioning plans that support the overall project schedule
- Developing commissioning documents (e.g. User Requirement Specification, inspection forms, Factory Acceptance Tests and Site Acceptance Tests)
- Inspecting for physical completion
- Vendor audits
- Witnessing vendor commissioning activities
- Managing the commissioning activities of vendors, construction contractors, owners, and contract resources.
- Executing commissioning activities for utility and process equipment systems in a manner that maximizes opportunities for leveraging with qualification activities.

## Qualification Services

### Validation Master Plans

ProPharma Group regularly develops both site Master Plans and project-specific Validation Master Plans. Our plans guide the entire project team toward the identified goals related to a facility that can be validated in compliance with all applicable regulations.

### Installation Qualifications

ProPharma Group is proficient in writing and performing Installation Qualification protocols to ensure that the equipment received is in good condition, as designed, and properly installed in the manufacturing environment.

### Operational Qualifications

We work together with our clients to develop and execute Operational Qualification protocols that ensure process equipment and ancillary systems are capable of operating within established limits and tolerances.

### Performance Qualifications

ProPharma Group validation consultants have extensive experience and all the equipment necessary for performance qualification of facility systems such as HVAC, High Purity Water (WFI, PW) and process gases of all types.

# Computer Systems Validation

Our computer validation group can assist you with the complete life cycle of services associated with Computer System Validation. We offer the following services:

## Specification Development

We can assist you in the development of computer system documentation in compliance with industry standards as well as Good Automated Manufacturing Practices® (GAMP), including:

- User Requirements Specifications (URS)
- Supplier/Vendor Audits
- Functional Specifications (FS)
- Design Specifications (DS)
- Validation Master Planning (VMP)
- Software Development Life Cycle (SDLC)

## System Design Services

Our professionals are trained to provide a full gamut of design services ranging from the initial concept through full system integration. Available services include:

- Design Review
- Unit Testing
- Integration Testing
- System Testing

## System Procurement and Installation

Our organization can assist in solutions for any size system including:

- Project Management
- Gap Assessment
- Risk Assessment
- Vendor Leveraging

## Commissioning, Qualification and Validation Services

We can provide document development and execution services for computer hardware or software systems large or small. These services include:

- Factory Acceptance Testing (FAT)
- Site Acceptance Testing (SAT)
- Commissioning Testing
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Requirements Traceability

System Type Expertise includes the following:

- Building, Facility, Utility Systems
- Infrastructure
- IT Applications
- Laboratory Systems
- Process Control Systems
- Enterprise Level Systems

## Customer Support and Training

Our team is available to provide on-going system support and training services to supplement your company's personnel resources including, but not limited to:

- Backup and Recovery
- Data Archiving
- Continuity Planning
- Disaster Recovery
- Periodic System Reviews
- Surveillance Audits
- ISO/QMS Reviews
- Best Practices Training
- SOP Development

Good Automated Manufacturing Practices® (GAMP) is a Registered trademark of the International Society for Pharmaceutical Engineering.

# Program Management

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- portfolio management
  - early & late stage drug/device development
  - technology transfer

Program Management creates a centralized, high-level management platform to assess, plan and execute complex programs that typically include multiple projects, each with timelines critical to getting your drug/device to market faster. ProPharma Group's Program Management services provide solutions to your needs in:

- Portfolio Management
- Early and late stage drug/device development
- Technology Transfer

## Program Management

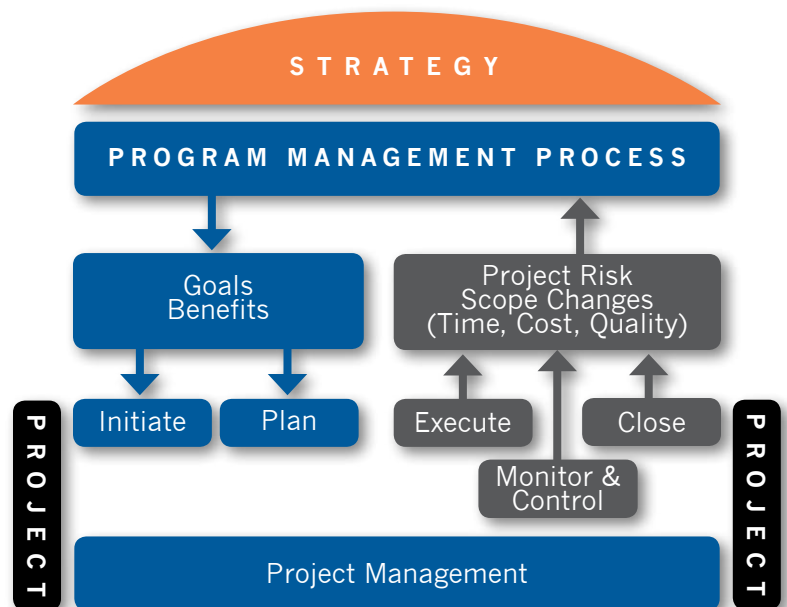
Our value-added services are offered in response to challenges that companies routinely face with moving a novel drug/device through the development continuum, transferring technologies between their manufacturing and partner sites, or outsourcing manufacturing to a Contract Manufacturing Organization (CMO).

**Program success is contingent upon having clear definitions and a concise strategy to provide a framework for building a Project Plan, including developing a realistic schedule while understanding the risks involved.** The Program Team must be capable of filling key roles and providing support for corporate processes in drug/device development and technology transfer. ProPharma Group's Program Management Services drive the process forward, improving an organization's performance and ability to meet program goals. These services include:

- Portfolio and Risk Management
- Project Prioritization
- Cross Project Planning and Scheduling
- Resource Planning
- Budgeting
- Communications Management
- Quality Management
- Development of the Program Management Organization (PMO)
- Performance Management
- Project Management
- Project Management Training
- Program Lifecycle Management

**ProPharma Group** brings to the table its multi-disciplinary team that has a ready-to-use toolbox of proven Project Management tools, required strategic knowledge, hands-on industry and regulatory experience, management and communication skills, and qualified Subject Matter Experts that contribute to the success of your program. By integrating performance measures, benchmarks and goals, organizational performance is monitored, measured, optimized and improved.

We can spearhead the due diligence process to answer critical questions and help you plan for, and reach a successful outcome, on time and within budget. ProPharma Group's Program Management Services drive the process; improving your organization's performance, providing sustained momentum to meet the organization's goals, and doing what is right for the business.



# Compliance & Quality Assurance

ProPharma Group realizes that the identification of Quality Assurance (QA) and Compliance problems is only part of the compliance puzzle; knowing what to do about them to mitigate risk is the key! As a provider of hands-on solutions, ProPharma Group offers the following value-adding QA and Compliance services:

## Quality Assurance

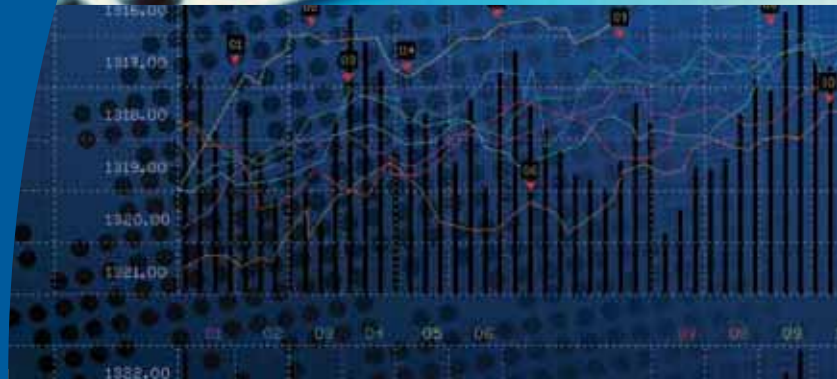
Our QA professionals have extensive experience in regulated environments and bring this value to the table when assisting our clients with their QA-related needs.

- QA/QC Staff Augmentation
- Policy, SOP and Batch Record Review, Preparation and Optimization
- Quality System (QS) Development, Assessment and Optimization
- QS Auditing / Benchmarking
- Corrective and Preventive Action (CAPA) Planning and Execution
- Training – FDA, GMP, QSR, Validation, Operator, Safety, etc.

## Compliance

Our Compliance professionals augment our clients' internal capabilities to prepare for, execute and address compliance-related observations and deficiencies, thus mitigating our client's regulatory risk.

- Third-party GMP and GLP Compliance Auditing
- Mock FDA/International Regulatory Agency Inspections and PAI Auditing
- Due Diligence Compliance Inspections, Audits and Assistance
- FDA Action (483 Observations, Warning Letters, Consent Decrees) Remediation

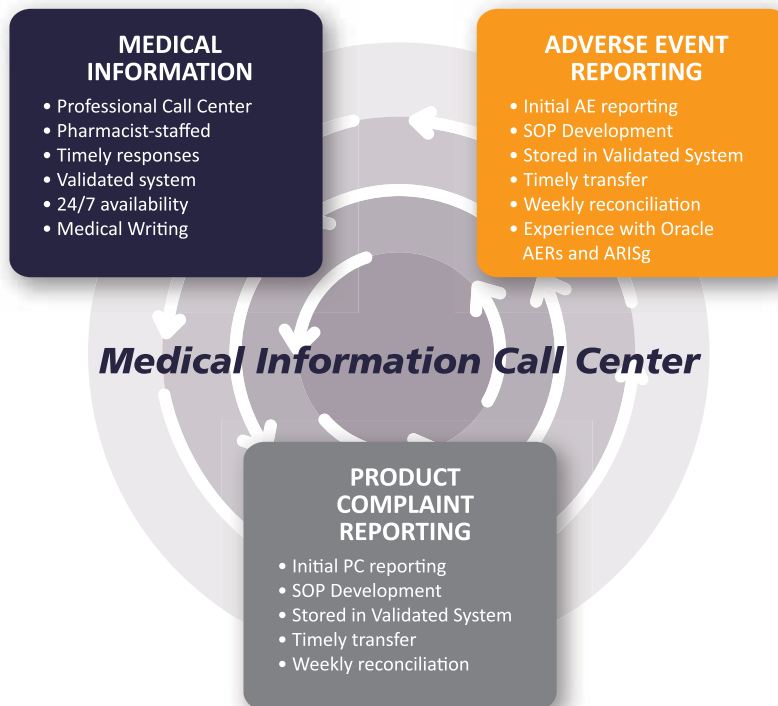


# Medical Information Services

Advanced Response Management (ARM), a wholly owned subsidiary of ProPharma Group, is an Integrated Medical Information Service provider. Established in 2000, ARM functions as a seamless extension to our clients, meeting the medical information needs of both biotechnology and pharmaceutical companies. In compliance with the established FDA guidelines, the pharmacists at ARM respond professionally to inquiries from healthcare professionals, patients and consumers.

## Core Activities

The pharmacists at ARM are highly trained with extensive experience in Medical Information. In addition, the pharmacists bring a wide variety of practical health care experience in the fields of hospital, retail and managed care settings. This practical experience assists the pharmacists in communicating the technical expertise regarding your company's products.



## Process Validation

Process validation is defined as establishing documented evidence that a specific process will reliably and consistently produce a product that meets its predetermined specifications and quality attributes. Processes could encompass manufacturing, filling, sterilization, and packaging within the FDA regulated pharmaceutical, biotechnology, API and medical device industries.

ProPharma Group employees have experience validating processes in all aspects of the FDA regulated industries.

We can review your development reports to assist in the determination of critical process parameters and quality attributes, and use this review to develop scientifically justified validation plans, which demonstrate consistency and reliability in processing. We can also assist you in developing statistically justified in-process and finished product sampling strategies. Knowledge of the critical processing steps, quality attributes and sampling strategies allows our process validation engineers to challenge the robustness of the process during the development and execution of the validation studies.

## Cleaning Validation

The prevention of cross contamination is an essential component of any GMP program and is necessary to ensure the safety of drugs, biologics and medical devices used in human or veterinary applications. A major source of contamination risk to these products is in the form of carryover of compounds and cleaning agent residues from the previous manufactured product or cleaning process. Properly designed and executed cleaning validation studies ensure that the process removes product and cleaning agent residues from product contact surfaces to an acceptable limit.

[ProPharma Group has the expertise to guide you through the cleaning validation process.](#)

We are experienced at developing and executing validation master plans and protocols abreast with current industry standards. We provide a hands-on group of professionals that can guide you through the details of establishing a cleaning master plan, setting residue acceptance criteria, preparing a comprehensive sampling plan and validating and utilizing appropriate analytical methods with sufficient sensitivity for those unique processes and equipment.

# Automation

Industrial and value-added automation services focused on improving quality and plant efficiency with expertise in:

- Automation
- Industrial control and computerized systems
- Plant and shop floor automation
- Manufacturing Execution Systems (MES)
- Enterprise Resource Planning Systems (ERP)

Our services include turnkey project implementation supporting, project management, complete design capabilities, selection of components, installation, simulation, commissioning, startup, and ongoing customer service and maintenance.

# Process Analytical Technology (PAT) Consulting

ProPharma Group has combined its extensive background in process validation and control systems to offer a complete PAT solution to clients. Dating back to 1998, ProPharma Group has helped clients bring their pharmaceutical manufacturing processes online to provide valuable information as production occurs, spanning everything from raw materials to batch release.

**ProPharma Group has developed a four phased approach to addressing the PAT Initiative**, based on the key principles defined by the FDA:

**Investigate, Develop, Implement and Monitor.** We see these four phases as cyclical as true compliance with the PAT Initiative is attained.

**Investigate:** We begin with an investigation into your current processes and systems in place to control, monitor and ensure quality of these processes. We then recommend an action plan.

**Develop:** By working together with you, we select and develop the solutions identified in the action plan. Solutions could include process instrumentation, analytical software, quality procedures and multi-variate analysis.

**Implement:** We will help you install, validate and go live with each solution. We team with your resources to perform such tasks as commissioning, qualification and training.

**Monitor:** We advise you on how to best monitor your implemented PAT solutions to ensure you are getting the results you need. We also help you decide when to return to the investigation phase and continue on the four phase cycle.

*ProPharma Group has assembled a team of consultants, partners and specialized experts to work together with you to understand and implement Process Analytical Technology solutions.*



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