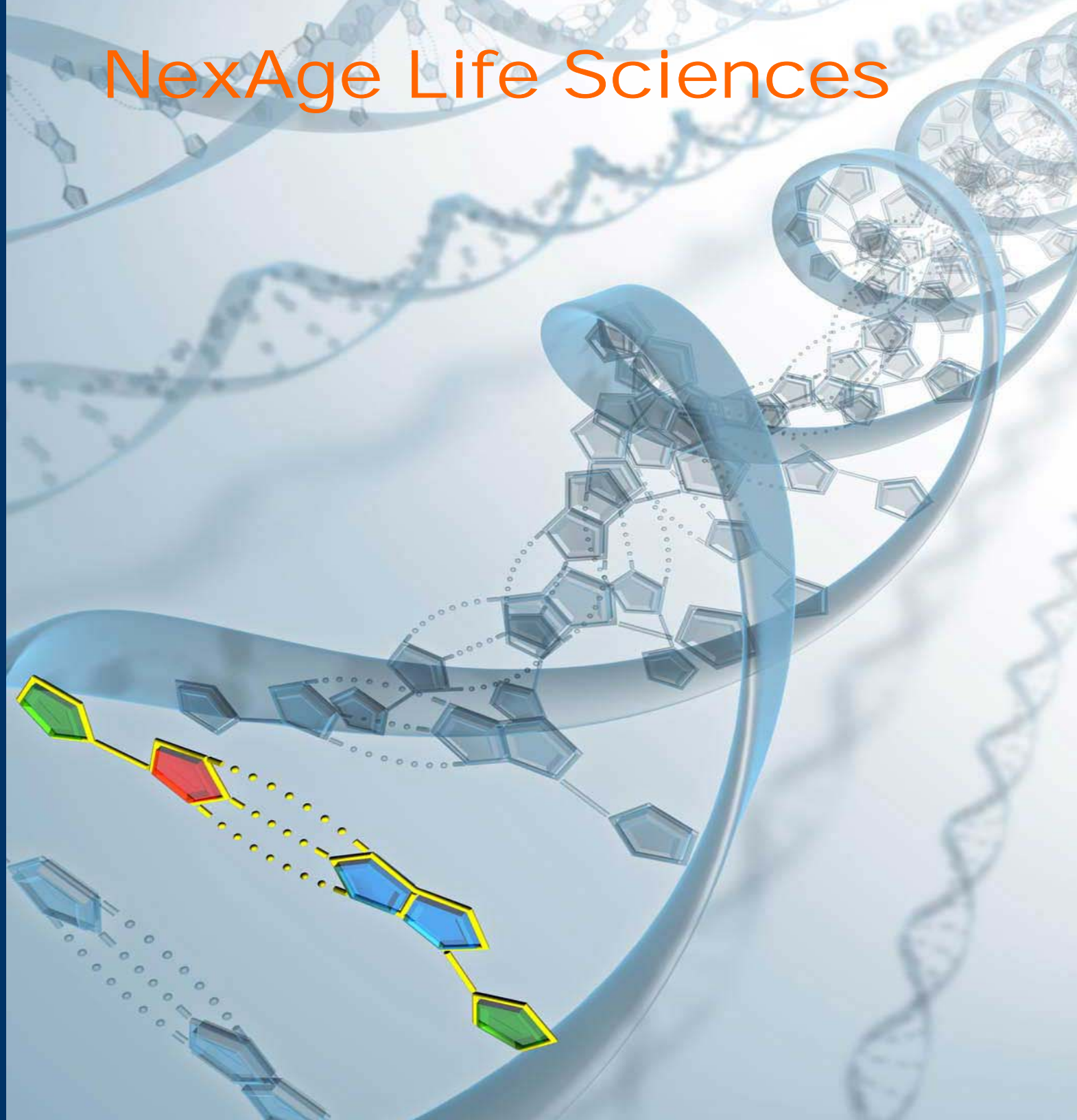


# NexAge Life Sciences

@  
the  
intersection  
of  
Life Sciences  
Compliance  
and  
Technology



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NexAge Life Sciences (NLS) is a division of NexAge Technologies USA Inc, a well established, global IT services organization. The company, headquartered in New Jersey is a certified minority owned business enterprise that specializes in consulting, project management and staffing services to the Life Sciences industry all across the US. The services provided by NLS include: Regulatory compliance, IT Audits, Validation services and Quality Assurance to FDA regulated industries including pharmaceutical, biotechnology & medical devices.

NexAge has been named as one of the 50 fastest growing Asian American firms in the US by the US Pan-Asian American Chamber of Commerce and is also ranked in the Inc 5000 list based on its revenue growth over the past 5 years. With its people centric business model, the company has built a strong reputation as the preferred destination for experienced professionals in the fields of Compliance, IT/Software and Management.

### Company Address and Contact Information:

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## Compliance in the Life Sciences Industry



GxP regulated industries have to plan, implement and document all validation activities not just from the standpoint of meeting critical compliance requirements, but also to enhance security, efficiency and profitability.

Validation provides the Life sciences industry many benefits, which include:

- Assurance of safe and quality products
- Reliable equipment and systems
- Processes that can be replicated
- Long term rewards associated with Quality Systems and Procedures

The more complicated State and Federal regulations become, the more challenging it becomes for life science companies to utilize computer systems in a fully compliant manner.

This situation creates several challenges such as:

- Identifying people with the right skill and experience and the related resources to stay up-to-date with rapidly changing regulatory developments and to be constantly prepared for an FDA audit/inspection.
- Meeting consumer demand for high quality standards at affordable prices under difficult economic environment.
- Balancing dual priorities of equal importance: the ongoing regulatory changes in the industry, with the implementation of new processes and technologies that are also compliant.

## NexAge Life Sciences: Your Partner in Success



Recruitment, training, development and deployment of in-house personnel to meet regulatory compliance requirements is always a costly proposition. By contrast, a partnership with an organization that specializes in compliance and validation allows Life Sciences organizations to meet the cyclical validation requirements, while freeing up valuable internal resources to focus on core business functions.

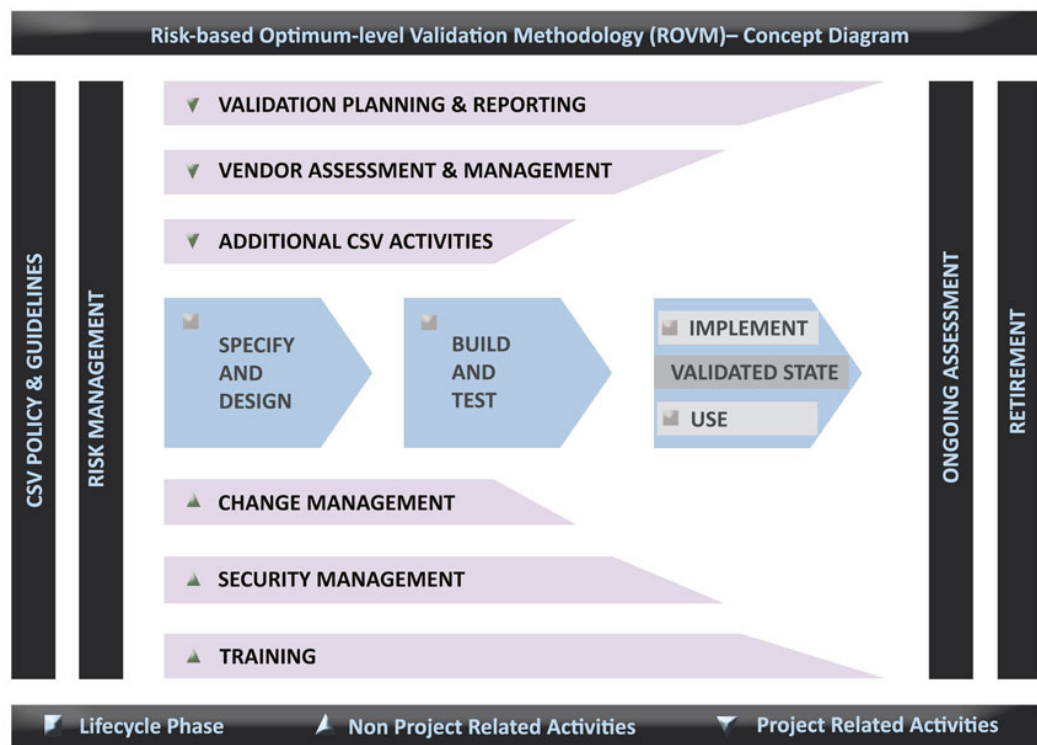
NLS service offerings include:

- Validation Strategic Planning
- Computer System Validation
- Creation of Corporate Policies and SOPs related to compliance
- Specialized Validation Training and Guidance
- Staffing (Temporary and Permanent)
- Independent Quality Management and Testing Automation
- IT Audits

### Why Partner with NLS?

- Direct access to subject matter experts having deep and relevant experience and current knowledge across a broad spectrum of validation and compliance practices
- Predictable costs through the implementation of clear roles and competence frameworks
- Elimination of validation bottlenecks, by taking it off the critical path of your projects, leading to faster project completion
- Access to independent auditing by a group of highly skilled compliance professionals.
- Ongoing collaborative review of validation procedures, securing timely opportunities to implement a risk-based validation methodology.

## Risk-based Optimum-level Validation Methodology (ROVM)™



For most Life Sciences organizations, meeting the requirements established for the Compliance and Validation of computer systems is not a task that can be easily handled in-house.

FDA Regulations as well as ICH Q9 has made reference to an expectation that risk management approaches would serve as a basis for Quality and Validation activities.

As a result NexAge Life Sciences (NLS) has developed the *Risk-based Optimum-level Validation Methodology (ROVM)*, which centers on the FDA and GAMP 4/5 promoted risk based approach.

The ROVM will help you to

1. Utilize your resources optimally
2. Operate in a structured manner
3. Gain regulatory compliance and business confidence
4. Implement a consistent approach to validation
5. Periodically assess the validation state of your systems.

With NLS as a strategic partner, you have an experienced, single-source provider delivering a comprehensive and cost-effective suite of validation services to help you keep your regulatory operations fully compliant.

Our validation teams keep abreast of current practices through our liaison with international clients, updates from regulatory authorities, participation in industry conferences, partnering with vendors and strategic involvement with the GAMP forum.

## Service Offerings

- Regulatory Compliance through Computer Systems and Equipment Validation Services
- Validation Strategic Planning
- Creation of Corporate Policies and Procedures for Compliance
- Risk Based - Information Technology Audits
- FDA Form 483 and Warning Letter Analysis, Corrective Actions and Implementation
- Specialized Validation Training
- Strategic Project Staffing



## Regulatory Compliance through Computer Systems and Equipment Validation Services

NLS provides a full range of Regulatory Compliance and Computer Systems Validation (CSV) services that are backed by the vast professional experience, deep industry knowledge, proven expertise of a large pool of senior professionals.

Proper validation is the key to any successful computerized system implementation. In order to achieve it, however, Life Sciences Organizations need in-depth knowledge, expertise/experience and a commitment to result oriented execution; three important qualities that NLS has established its reputation upon.

The validation planning, implementation and evaluation strategy of NLS is based on applicable regulations and guidelines for product and processes of the organizations.

Services offered in our validation program include:

- Validation Documentation
- Project Management
- Life Cycle Analysis and Review
- Risk and Criticality Assessments
- Validation Program Development
- Qualification Protocol Preparation and Execution
- Standard Operating Procedures (SOPs) Development
- Business Continuity Plans
- Disaster Recovery Plan

## Validation Strategic Planning

Through a well-defined, systematic risk management approach, NLS helps clients determine the appropriate validation requirements based on organizational needs and how systems are used. We assist Life Sciences organizations assess their systems and determine what level of documentation and testing is appropriate, identify issues, and set priorities for resources.

As part of a comprehensive risk management strategy, NLS works with clients to develop an on-going management process for assessing new systems and to monitor and re-assess existing systems with the objective of ensuring compliance in the ever-changing regulatory and business environment.

## Creation of Corporate Validation Policies

Often within Life Sciences organizations, the questions arises as what needs to be validated and when. NLS develops and delivers corporate validation policies and procedures at the operational and project levels.

Services offered:

- Develop Company Policies for Computerized System Validation
- Develop SOPs for Validation Package Management (IQ/OQ/PQ), Formal Testing Practices, and Business Review
- Design Quality Management Systems for Validation
- Enhance your existing IT Audit and Security Policies and Procedures

## Service Offerings... *continued*

*"We view Compliance and Risk Management - in a regulated environment and in IT governance- as key management priorities that cut all functional departments of the organizations and all committees of the board. Therefore it is critical that the responsibility for meeting compliance standards and for managing risk is transparent and can be fixed at all levels."*

Dr. M. V. Pillai  
Chairman, NexAge Life Sciences

### **Risk Based - Information Technology Audits**

NLS teams provide clients with the following services that will result in dynamic, documented and tested IT Controls and Procedures:

- Analysis of existing Internal Controls and Procedures
- IT Infrastructure Risk Assessment
- Computer Application Audit
- Software Licensing Compliance Audits
- Creation of IT Infrastructure Checklist
- SDLC Participation
- Business Continuity Plan and/or Disaster Recovery Plan Audits
- Excellent documentation of IT Policies and Procedures
- Provide Training on Internal Controls and Procedures to IT staff.

### **FDA Form 483 and Warning Letter Analysis, Corrective Actions and Implementation**

NLS offers clients confidential consultations on FDA Form 483 and/or Warning Letters to help with the following::

- Analyzing the deficiencies listed in FDA-483 and/or Warning Letter received from FDA
- Recommend Corrective Actions to the deficiencies.
- Suggest a timeline to apply the Corrective Actions
- Assist in implementing the Corrective Actions
- Perform Periodic Reviews and mock FDA Inspection Audits of your Quality Systems and Quality Procedures to avoid any future FDA Warning Letters.

### **Specialized Validation Training**

Well-trained employees are critical to successful business planning and execution. NLS provides specialized validation training services for all levels of client personnel.

Onsite Corporate Training brings "High-Impact" quality and compliance training to your organization. Our onsite seminars and workshops are customized to your industry and training goals. Facilitators are specifically chosen based on their expertise and understanding of client training needs. We develop customized and cost effective onsite training solution for organizations of all sizes.

Fundamental or in depth training seminars can be delivered on-site or at an NLS location.

### **Strategic Project Staffing**

NLS has team of experienced full-time professionals who specialize in validation, compliance and IT audit for the Life Sciences industry.

Our professionals possess the capability of assuming the leadership in project planning and executing compliance programs. We work in collaboration with the operational personnel, the IT department or other contractors/vendors of our clients

Our strategic staffing services are offered either on a contract basis with a right to hire provision. What makes our staffing services compelling to clients is our highly competitive pricing model and the guarantee we offer, which set us apart from our competition.

# An Invitation to Partner

*"Trust is so central to all our relationships that we work very hard to establish, grow and if required to restore it. We believe that Trust is the not just a soft virtue, but is a game changing economic driver that give us a clear competitive advantage".*

Suresh U Kumar  
CEO, NexAge Life Sciences



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It has been our experience that most Life Sciences Organizations do have a variety of internal systems and external vendor partnerships in place to address their compliance and validation issues. To assess real value, we recommend that organizational leaders ask the following key questions:

- Does existing arrangements meet organizational growth needs?
- Are you getting the best value for money?
- Is the current partner dependable and reliable at all times?
- Is there a process in place to ensure knowledge transfer to key employees?

## **What value does NLS bring to the table?**

The most critical value addition we provide is the deep understanding of the various challenges that cGxP regulated industry face and providing cost-effective solutions. Through our well thought through methodologies, we bring you years of relevant experience. As a committed team of validation and regulatory compliance specialists, we have you covered in almost all aspects of compliance and validation. We are committed to deliver the high level of compliance required by Life Sciences organizations. Our goal is simple: to earn the trust of our clients by consistently exceed expectations. Our industry knowledge, integrity, excellence in execution, competitive pricing models and quick results are distinct advantages that makes our value proposition compelling

Please contact us to schedule a complimentary meeting with our compliance specialists. We invite you to partner with us.