NNIT 质量管理解决方案

NNIT Quality Management Solution

质量管理 Quality Management

- **IT 质量管理体系及数据完整性咨询**
  IT Quality Management and Data Integrity Consulting
- **质量管理系统**
  Quality Management System (QMS)
- **文档管理系统**
  Document Management System (DMS)
- **无纸化验证解决方案**
  Validation Lifecycle Management System
- **计算机化系统验证 & 计算机软件保证**
  CSV & CSA
- **生产设备/设施/工艺/实验室验证**
  Production&Lab CQV
- **IT基础架构确认**
  IT Infrastructure Qualification

IT 质量管理体系及数据完整性咨询

IT Quality Management and Data Integrity Consulting

痛点及应用场景
Pain point and application scenarios

DI—不断上升的业界关注焦点
DI - Rising Industry Focus

信息化建设的不断完善
Continuous improvement of information technology construction

审计过程的越来越多的发现项
More and more discoveries in the audit process

法规指南的不断提及
Continuous mention of Regulations and Guidelines

有关DI的问题
Issues on DI

恶意或意图数据修改/删除
Malicious or intentional data modification/deletion

操作/流程缺陷
Operational/process defects

系统功能缺失
System functionality is missing

NNIT质量管理体系及数据完整性解决方案优势

Advantages of NNIT Quality Management and DI Solutions

参与编写了NMPA现行版GMP附录-计算机化系统

Participated in drafting the appendix of GMP - Computerized System Management

连同国家药监局及多家省局为GMP检查员进行培训

Together with the CQAP, popularized CSV knowledge for pharmaceutical enterprises

了解FDA, NMPA等机构审计重点

Understand the audit focus of institutions such as FDA and NMPA

专注深耕医药行业

近 30 年

Focusing on deepening the pharmaceutical industry near 30 years

帮助医药行业客户通过FDA, NMPA审计

近 100 次

Helping pharmaceutical industry clients pass FDA and NMPA audits nearly 100 times

服务客户项目

超 500 个

Serving over 500 customer projects

ISPE | Gamp RECORDS AND DATA INTEGRITY

Core Team

The following individuals took lead roles in the preparation of this Guide:

John Andrews	Andrews Consulting Enterprises, Ltd.
Karen Ashworth*	Karen Ashworth Consulting, Ltd.
Reetu Chopra	Teva Pharmaceutical Industries, Ltd.
Kristina Dimitriadis	Werum IT Solutions GmbH
Brian Frederiksen	NNE
Željko Granoša	Pliva Croatia, Ltd.
Paul Irving	Northern Life Sciences Ltd.
Hilary Mills-Baker	Emerson Automation Solutions
Steve Murray	Werum IT Solutions
Gregory Ruklic	Independent Consultant
Catherine Smillie	Sharpe Solutions & Compliance Ltd.
David Stokes	Convalido Consulting Limited
Rajesh Thempadiyil	Dr. Reddy's Laboratories, Ltd.
Anders Vidstrup	NNIT A/S
Christian Wolbeling	Werum IT Solutions GmbH

GOOD PRACTICE GUIDE:

Data Integrity – Manufacturing Records

NNIT质量管理体系及数据完整性解决方案

NNIT Quality Management and DI Solutions

1 **质量管理体系搭建（改造）**
Quality management system construction (renovation)

2 **ITQA/ITQC外包**
ITQA/ITQC outsourcing

3 **数据完整性咨询（审计）**
Data integrity consultation (audit)

4 **IT GxP运维**
IT GxP operation and maintenance

5 **验证监理**
Validation inspect and control

6 **GxP合规培训**
GxP compliance training

质量管理系统

QMS

质量管理痛点
Pain point in Quality Management

1.药品工艺复杂，监管要求趋严
Complex pharmaceutical processes with increasingly stringent regulatory requirements

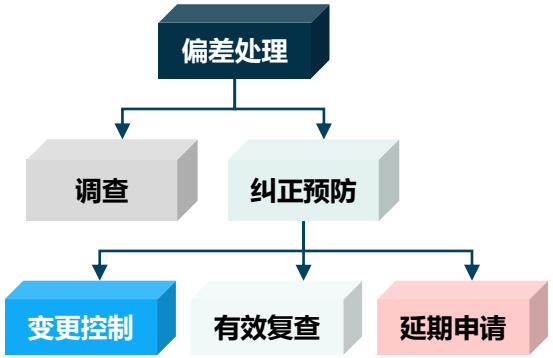
2.药品质量，生产效率，生产成本周期之间的平衡
The balance between drug quality, production efficiency, and production cost cycle

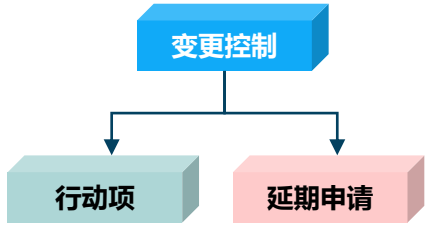
3.客户满意度与品牌忠诚度的挑战
Challenge of customer satisfaction and Brand loyalty

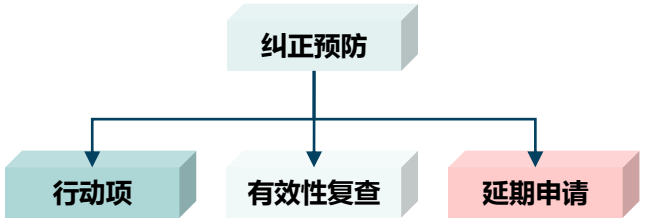
4.复杂的供应链管理
Complex supply chain management

方案概览
Solution Pitch

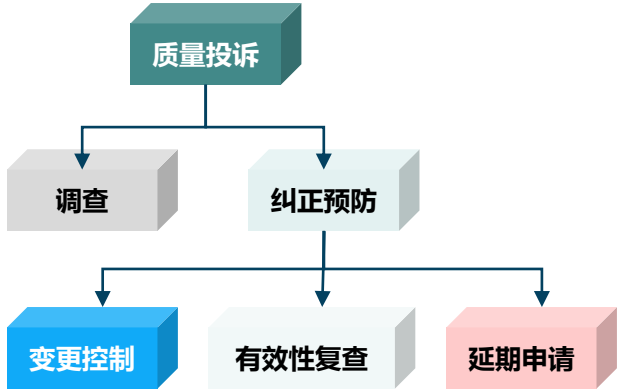
第一阶段：

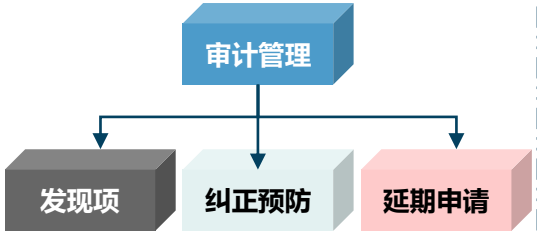


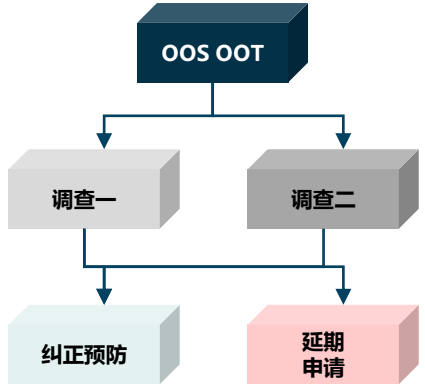




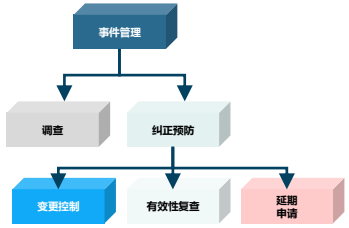
第二阶段：

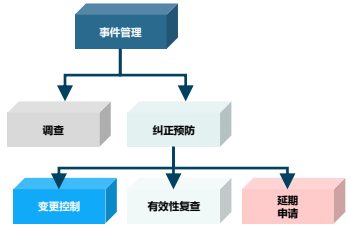


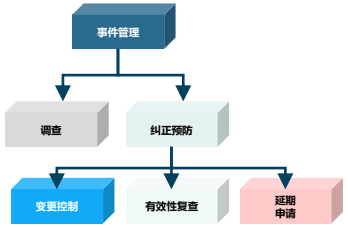


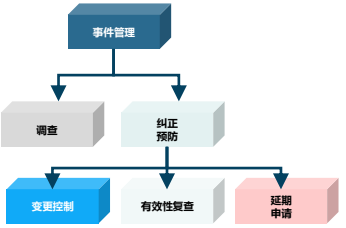


第三阶段：









eQMS解决方案--Trackwise
eQMS Solution--Trackwise

生命科学企业部署TrackWise的潜在收益:
Potential Benefits of Deploying TrackWise for Life Science Enterprises

@ 提高质量事件与潜在趋势的预见性
Improve the predictability of quality events and potential trends

@ 完善问责制度、管控与透明度
Improve the accountability system, control, and transparency

@ 实现高品质与合规性
Achieving high quality and compliance

@ 杜绝记录、数据或文档丢失的可能性
Eliminate the possibility of loss of records, data, or documents

@ 减少非增值活动所耗用的时间
Reduce the time spent on non-value-adding activities

@ 加速质量问题的解决与完成
Accelerate the resolution and completion of quality issues

@ 集中高效统一管理所有质量流程
Centralized, efficient and unified management of all quality processes

NNIT专业提供
Professional services out of NNIT

TrackWise的咨询与部署
◉全球顶级的EQMS流程设计;
◉高度灵活性实现SOP客制化需求;
◉符合行业监管要求。

TrackWise的运行与管理
◉提供全面的后续运行;
◉系统维护和技术支持;
◉配置调整、数据管理、季度报表等。

TrackWise项目的专业验证服务
◉行业认可的基于风险的验证服务;
◉确保合规性并支持灵活的运营;
◉提高业务效率。

文档管理系统

DMS

痛点及应用场景
Pain point and application scenarios

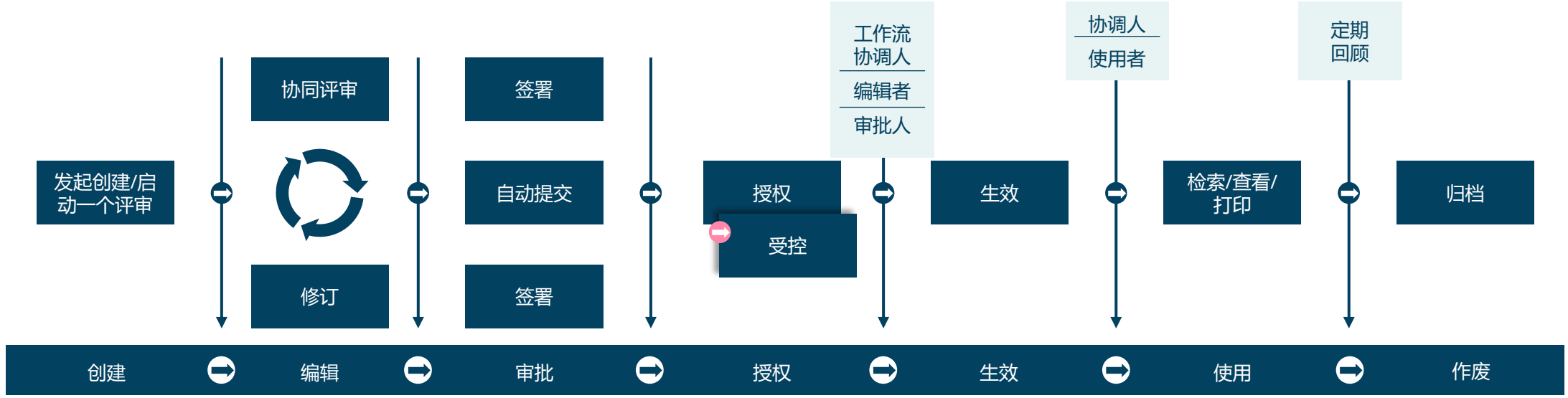
◉合规挑战：传统方式下的文档管理缺乏制度流程导致不受控
Compliance challenge: The lack of institutional processes in traditional document management leads to uncontrollability;

◉复杂的GxP文档要求
Complex GxP document requirements;

◉文件编号与版本控制混乱；
Chaotic document numbering and version control;

◉文档放行失控；
Document release out of control;

◉文档内容难访问：分享与查阅繁琐复杂；
The content of the document is unreachable: sharing and consulting are cumbersome and complex;



方案概览
Solution Pitch

Life-Cycle文档管理

- **灵活可配置的工作流与审批流**
  Flexible and configurable workflows and approval processes;
- **自动提醒与文档发放；**
  Automatic reminders and document distribution;
- **可配置的报告输出；**
  Configurable report output;
- **可追溯的问责；**
  Traceable accountability

- **支持电子签名和审计追踪；**
  Support electronic signatures and audit trails;
- **支持高级文档检索；**
  Support advanced document retrieval;
- **支持版本控制**
  Support version control

无纸化验证解决方案

Validation Lifecycle Management System

痛点及应用场景
Pain point and application scenarios

基于纸质的药企合规验证活动现状
Typical issues related to paper-based validation

高成本
High Costs

- 验证项目周期长
  Lengthy cycle time
- 大量文档工作
  High documentation requirements
- 缺乏文档工具
  no common documentation tool
- 遵循GDP的高成本
  GDP practice challenges
- 复杂的验证流程和活动
  Cumbersome validation processes and activities

合规挑战
Compliance Challenges

- 纸质文件丢失或错放
  Lost or misplaced paper records
- 缺乏可追溯性
  Lack of traceability
- 签名纸质文档打印和扫描
  Poor scan and print quality of signed paper documents
- 不符合数据完整性要求
  Lack of compliance with Data Integrity requirements

缺乏灵活性
Limited flexibility

- 验证资源/验证专家瓶颈
  Bottle-necks as validation documentation is tied to individuals
- 难以规划资源
  Difficult to plan resources
- 资深验证顾问将50%的时间花在非增值活动上
  Skilled resources spending 50% of time on non-value-added activities

缺乏标准化
Lack of Standardization

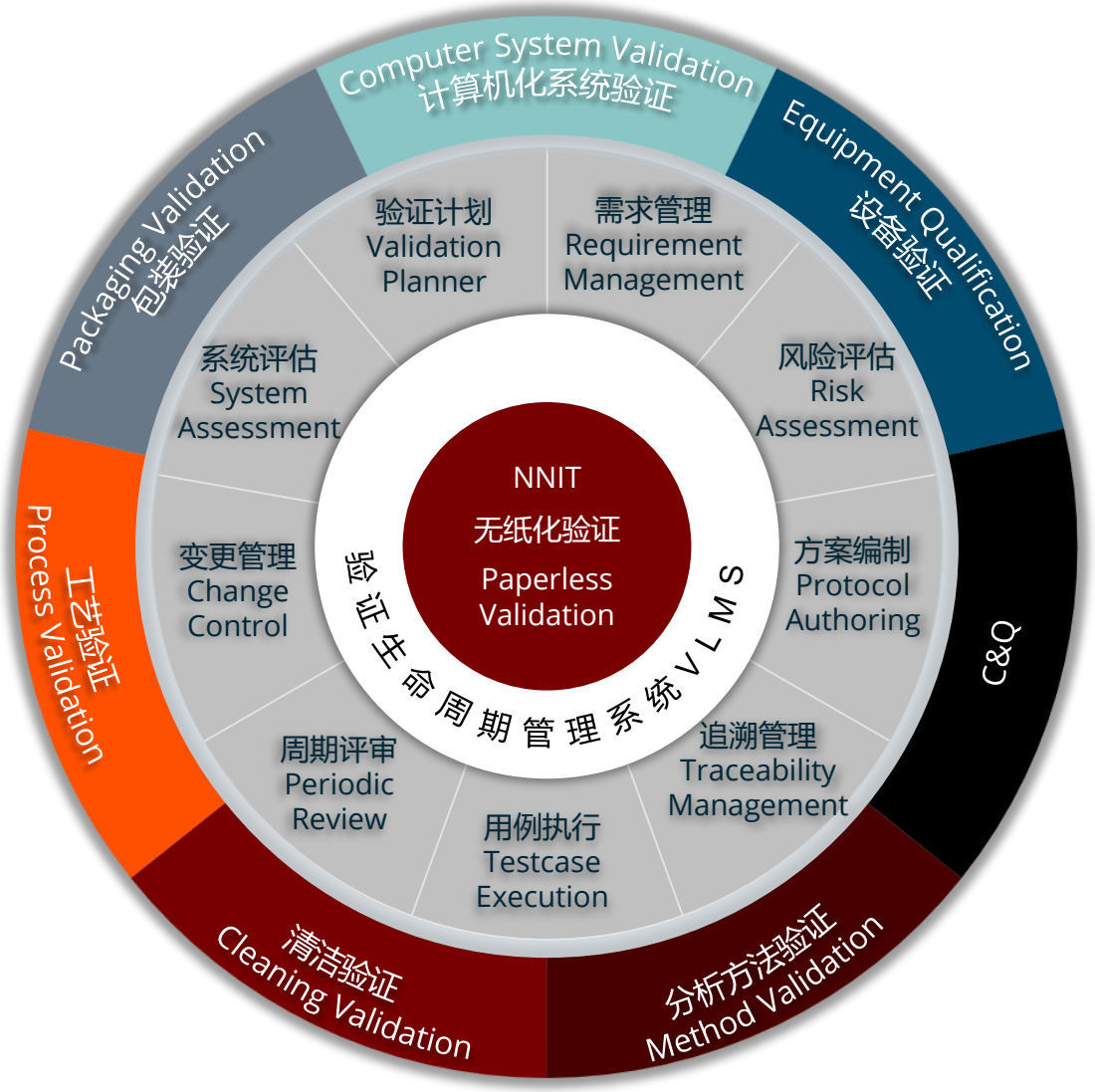
- 组织内验证流程难统一
  Diverse validation processes and practices across the organization
- 验证实践改进难推动
  Difficult to drive improvements and alignments of practices
- 验证项目难管理
  Difficult to manage validation projects
- 组织级别的批准难实现
  Difficult to enforce approved validation plans and procedures across the organization

方案概览
Solution Pitch

验证生命周期管理系统 VLMS
Validation Lifecyle Management System (VLMS)

全球生命科学行业验证无纸化的引领者和领先方案。支持全部验证类型，帮助您实现验证标准化、符合法规要求、减少错误和风险、降低验证成本、提高协作效率，保证验证过程透明化、自动化和可追溯。

ValGenesis VLMS is the industry standard digital validation platform for life sciences worldwide. Peerless in capability, it empowers you to enforce standardization, ensure data integrity, reduce risk, lower the cost of quality, and strengthen your compliance posture.



计算机化系统验证 & 计算机软件保证

CSV & CSA Solution

痛点及应用场景
Pain point and application scenarios

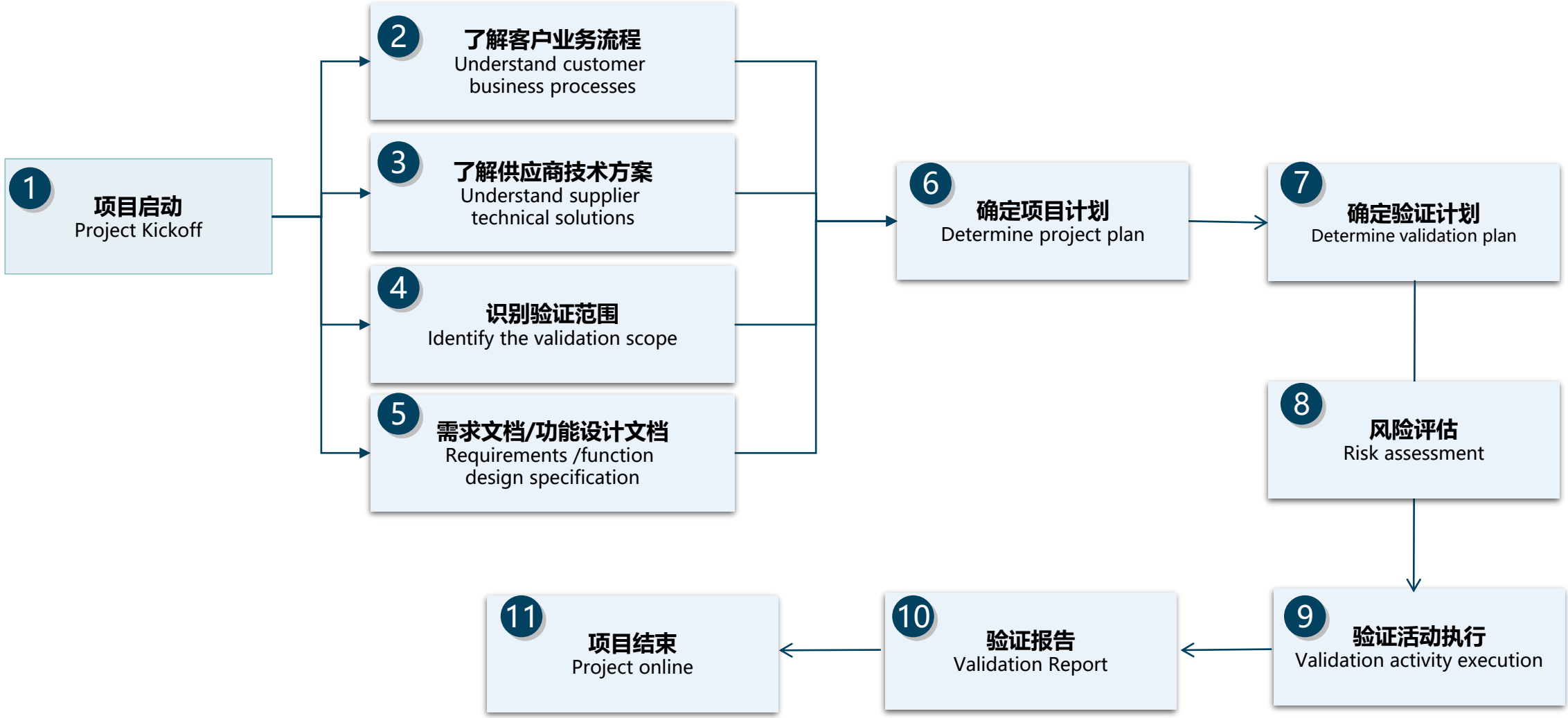
合规监管挑战
The Challenges of Compliance Regulation

- 记录真实性 Authenticity of records
- 审计追踪无法描述 Audit trail cannot be described
- 内审外审 Internal and external audits
- 系统访问控制 System access control
- 数据转录 Data transcription
- 超级管理员权限 Super administrator access

验证范围广泛
Extensive scope of validation

- 全生命周期管理 Full lifecycle management
- IT基础架构确认 IT Infrastructure qualification
- 风险管理 Risk management
- 系统运行 System operation
- 供应商管理 Supplier Management
- 变更和偏差 Change and deviation
- 审计追踪，电子数据，电子签名
  Audit trail, electronic data, electronic signature
- 备份归档和恢复 Backup archive and recovery
- 周期性回顾 Periodic Review
- 补充验证 Supplementary validation

方案概览
Solution Pitch



生产设备/设施/工艺/实验室验证

Production & Lab CQV

痛点及应用场景
Pain point and application scenarios

如何验证众多不同类别不同功能的设备?
How to validate numerous devices with different categories and functions?

如何验证每一项URS，覆盖所有RA?
How to validate each URS and cover all RAs?

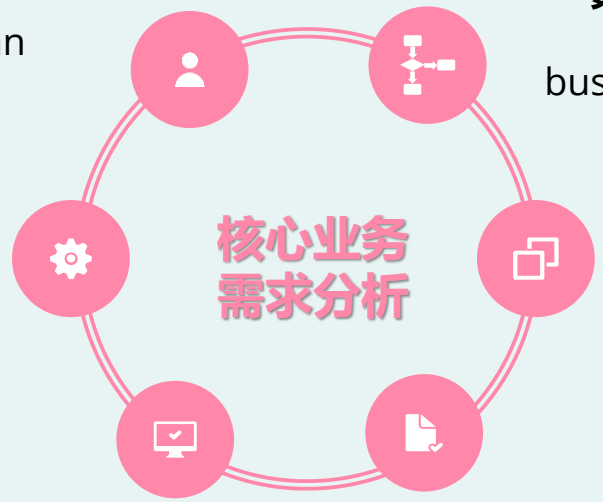
如何满足合规和数据完整性要求?
How to meet compliance and Data integrity requirements?

如何进行工作计划并减少偏差?
How to plan work and reduce deviations?

权限管理
authorization management

仪器性能
Instrument performance

风险评估
risk assessment



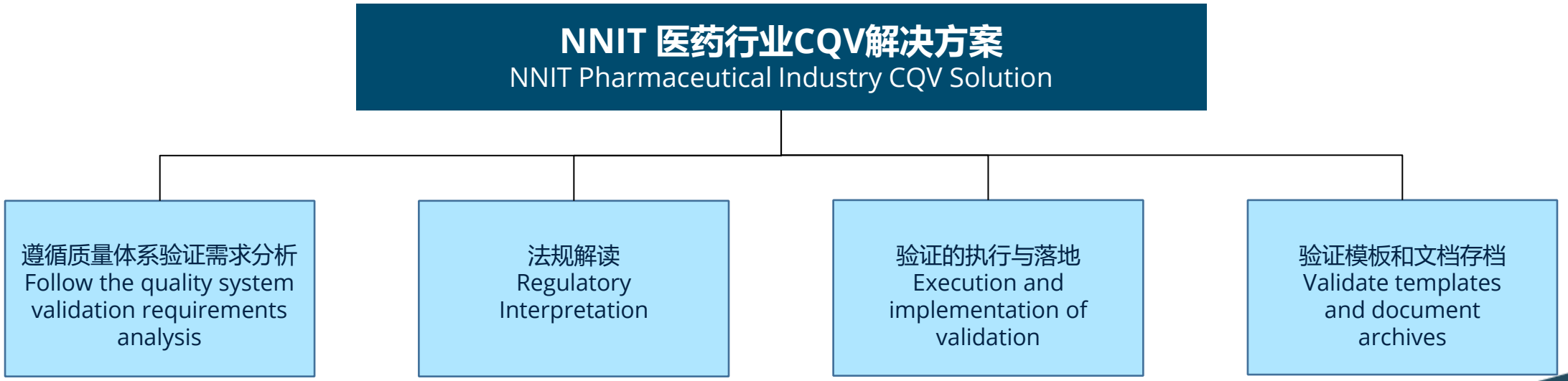
数据流和业务流分析
Data flow and business flow analysis

变更偏差控制
Change & Deviation Control

合规需求
Compliance requirements

方案概览

Solution Pitch



1

遵循客户或NNIT质量体系，助力药企完善验证需求分析Follow the customer or NNIT quality system to assist pharmaceutical companies in improving validation requirement analysis

2

深入解读行业法规及质量要求，按照合规的业务管控流程，出具验证计划Deeply interpret industry regulations and quality requirements, follow compliant business control processes, and issue verification plans

3

按照验证计划，制定满足业务执行，法规要求的验证解决方案和测试用例Develop validation solutions and test cases that meet business execution and regulatory requirements in accordance with the validation plan

4

存档验证模板和文件，以满足业务的扩展需求 Archive validation templates and files to meet business expansion needs

NNIT 生产设备/设施/工艺/实验室验证解决方案优势

Advantages of NNIT Production & Lab CQV Solutions

20+

验证顾问

专业的验证团队

- 专业IT背景验证顾问
- 实验室背景验证顾问
- 厂商背景验证顾问

100%

经验

全面的CQV验证经验

- 40+C类实验室仪器经验
- 熟悉GxP法规要求，Gamp5
- 厂商背景验证顾问

公用工程系统验证

- 纯化水制备与分配
- 注射用水制备与分配
- 纯蒸汽制备与分配
- 压缩空气制备与分配

生产设备设施验证

- 洗瓶机
- 隧道式烘箱
- 无菌罐装
- 冻干机

仓储设备设施验证

- 冷库
- 恒温室
- 常温库

洁净空调系统验证

- 洁净空调系统
- 洁净室
- 层流罩
- 传递窗

包装设备设施验证

- 内包装机
- 贴标机
- 装盒机
- 装箱机

实验室设备设施验证

- Agilent
- Thermo
- Molecular Devices
- Waters...

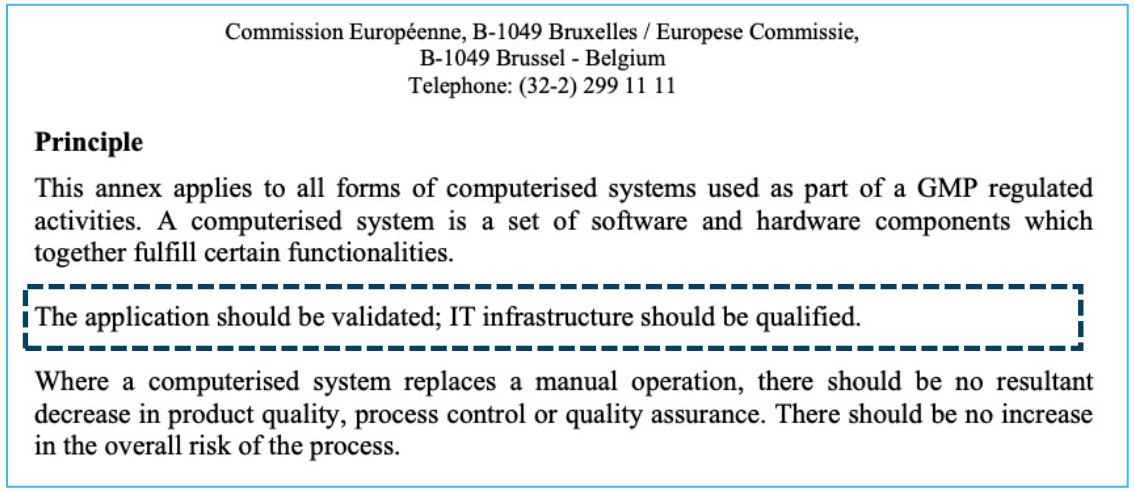
IT基础架构确认

IT Infrastructure Qualification

IT基础架构确认的必要性

The necessity of IT infrastructure qualification

欧盟 EMA Annex 11:
Computerized Systems



Commission Européenne, B-1049 Bruxelles / Europese Commissie,
B-1049 Brussel - Belgium
Telephone: (32-2) 299 11 11

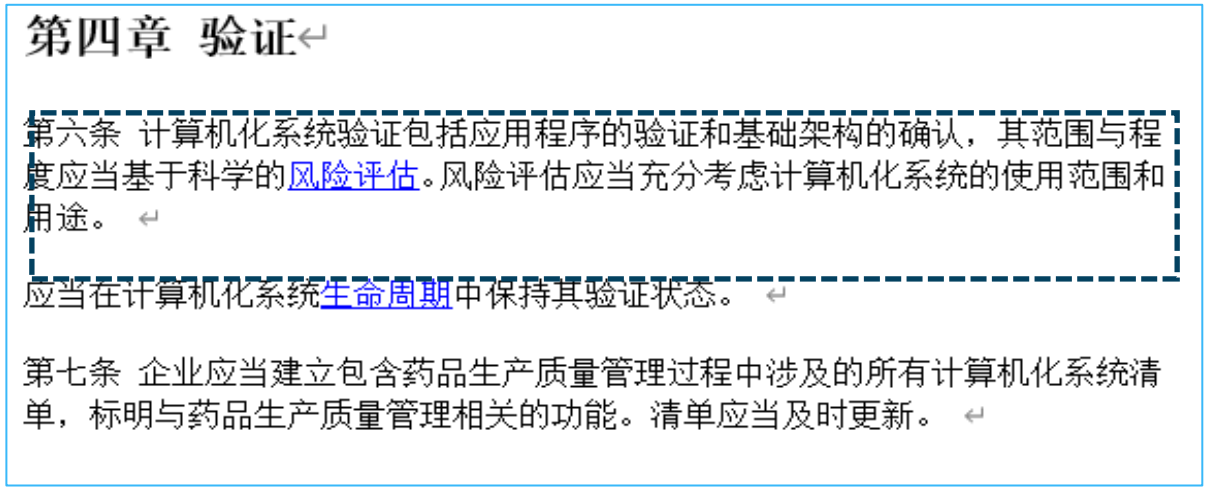
Principle

This annex applies to all forms of computerised systems used as part of a GMP regulated activities. A computerised system is a set of software and hardware components which together fulfill certain functionalities.

The application should be validated; IT infrastructure should be qualified.

Where a computerised system replaces a manual operation, there should be no resultant decrease in product quality, process control or quality assurance. There should be no increase in the overall risk of the process.

中国GMP 药品生产质量管理规范（2010年修订）附录：
计算机化系统



第四章 验证

第六条 计算机化系统验证包括应用程序的验证和基础架构的确认，其范围与程度应当基于科学的风险评估。风险评估应当充分考虑计算机化系统的使用范围和用途。

应当在计算机化系统生命周期中保持其验证状态。

第七条 企业应当建立包含药品生产质量管理过程中涉及的所有计算机化系统清单，标明与药品生产质量管理相关的功能。清单应当及时更新。

在欧盟Annex 11和中国GMP法规附录，计算机化系统中都明确提出：计算机化系统验证包括了应用程序的验证和基础架构的确认。

In both the EU Annex 11 and the Chinese GMP regulatory appendix, the computerized system clearly states: Computerized system validation includes application validation and infrastructure validation.

NNIT IT基础架构确认解决方案优势

Advantages of NNIT IT infrastructure qualification Solutions

验证能力+IT技术能力=IT基础架构合规

Validation capability+IT technology capability=IT infrastructure compliance

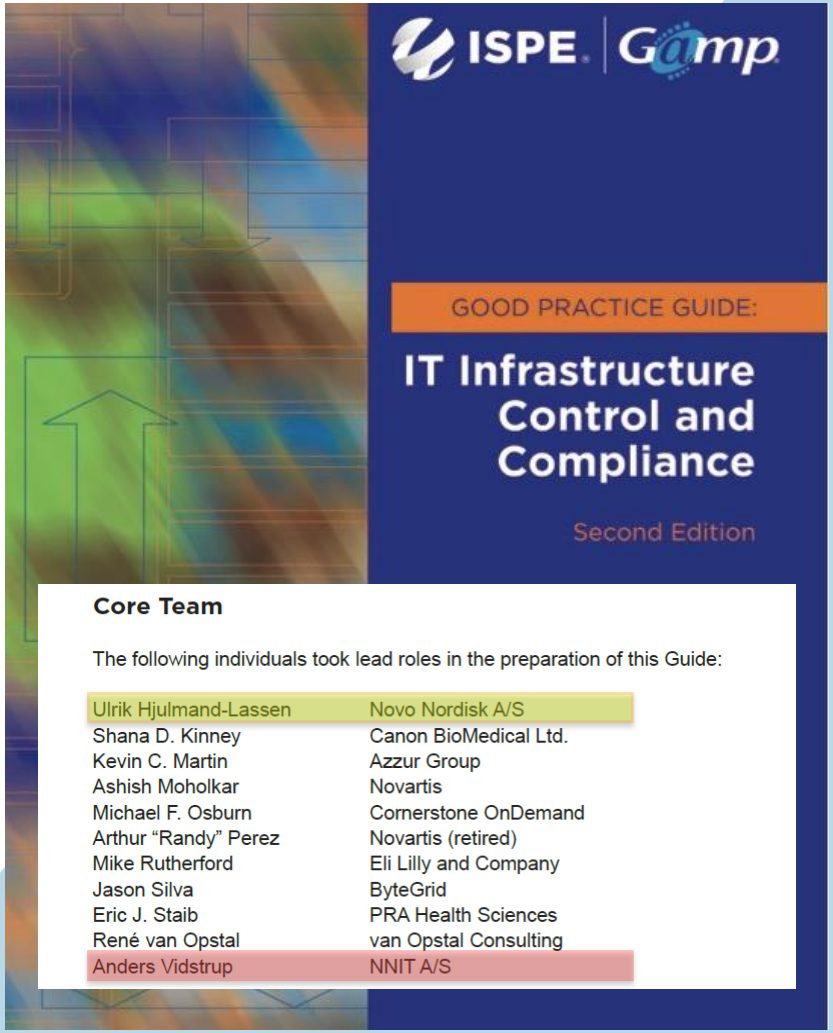
IT 基础架构实施，运维及确认范围包括:

The scope of IT infrastructure implementation, operation and maintenance, and confirmation includes:

- IT/OT网络架构及网络安全设备设施 IT/OT network architecture and network security equipment facilities
- 虚拟化/超融合平台 Virtualization/ Hyperfusion Platform
- 服务器存储设备 Server storage device
- 备份系统 Backup System
- 域控服务 AD Services
- 远程服务 Remote Services
- 标准时钟服务 NTP Service
- 杀毒服务 Antivirus services
- 应用监测服务 Application monitoring service
- 补丁服务 Patch service
- 数据中心场地环境（动环监控、配电、暖通、消防、门禁、视频监控）等 Data center environment (dynamic environment monitoring, power distribution, HVAC, fire protection, access control, video monitoring), etc

IT基础架构确认核心起草者

IT Infrastructure Qualification Core Team Member



NNIT 质量管理解决方案团队概览

Validation Team Pitch

50余名验证顾问
平均工作经验超过8年
More than 50 validation consultants with an average work experience of over 8 years

顾问均持有ISTQB认证
Verification consultants with ISTQB certification

全球团队定期法规知识共享
Regular regulatory knowledge sharing among global teams

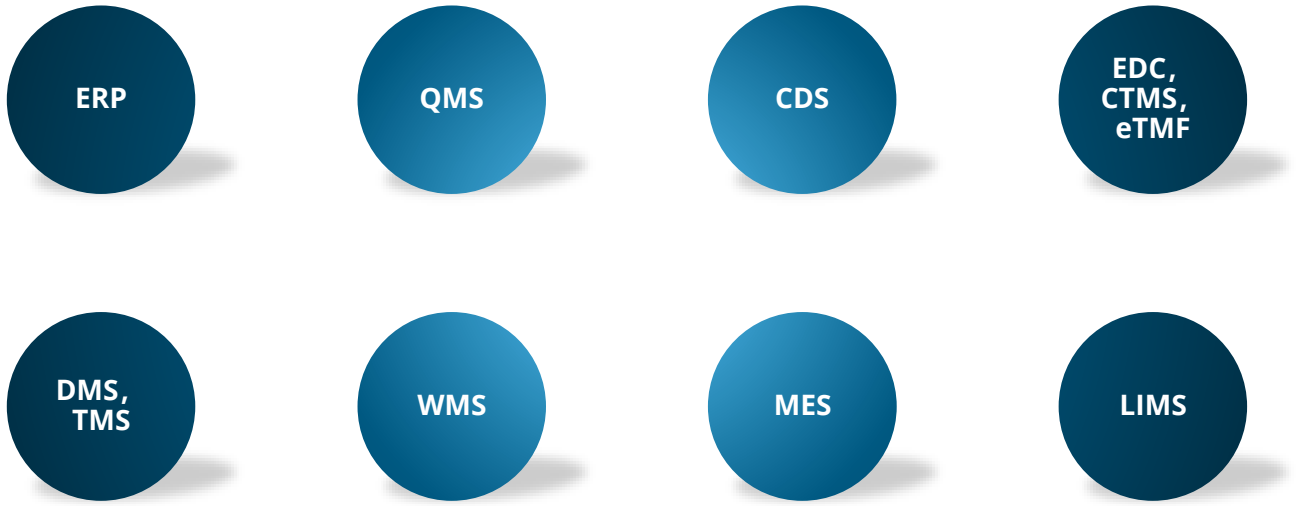
每月有30+验证项目在进行中
Over 30 validation projects are ongoing every month

30+人具有PMP认证
30+consultants with PMP certification

熟悉 GAMP5
Familiar with GAMP5

严格的内训和评估制度
Strict internal training and evaluation system

验证过的系统包含：
The verified system includes：



NNIT 质量管理解决方案客户案例

Customer cases of NNIT Quality Management Solutions

NNIT 质量管理解决方案

Contact
QR Code

扫码添加联系人
Scan the QR code to add the contact into your WeChat list

Tele No.: 022-58856725
Email: nnitchinamarketing@nnit.com
Website: www.nnit.com/cn
Location: Tianjin, Shanghai, Beijing