



Thermo Scientific TruScan RM and microPHAZIR RX

- Incoming raw material identification
- Material verification at the point of dispensing
- Finished product inspection
- Packaging material identification

Achieve quality initiatives
**throughout the
manufacturing process**

Thermo
SCIENTIFIC

Overview

Raw material inspection is a critical step in the quality control process with tremendous impact on customer safety as well as speed and cost of production. Global pharmaceutical manufacturers are seeking technology that will allow them to approach a 100% raw materials inspection goal, without prohibitive financial or staffing investments.



In this ever expanding and competitive market, it is now more critical than ever to implement efficient ways to ensure the quality of materials throughout the manufacturing process. From verifying the identity of raw materials at the point of receipt, to a dispensing booth in a plant where APIs are being manufactured, to the addition of excipients during secondary manufacturing, and all the way through finished product inspection – material identification is mission critical to sustaining product quality, while positively affecting throughput and production costs, and, ultimately, helping to ensure consumer wellbeing.



With portable instrument centers of excellence located around the world and local representatives located in more than 123 countries, we have the experience and global reach to ensure success.



Pharmaceutical Manufacturing Challenges

- Increased regulatory scrutiny
- Mounting quality assurance initiatives
- The drive toward lean manufacturing
- Global supply chains increasing the risk of supply chain variability

Thermo Scientific handheld solution

Developed with in-depth pharmaceutical industry experience, Thermo Scientific handheld analyzers provide manufacturers with a portable solution to achieve quality initiatives throughout the manufacturing process.

The Thermo Scientific TruScan RM, based on Raman spectroscopy, and the Thermo Scientific microPHAZIR RX, based on Near-Infrared (NIR) spectroscopy, are simple to use and enable on-the-spot, actionable Pass/Fail results within seconds.

With TruScan® RM and microPHAZIR® RX, pharmaceutical manufacturers can now obtain fast, accurate material identity verification with ease and convenience. These cost-effective solutions allow users to quickly develop methods, enabling immediate release of raw materials into production. Additionally, both analyzers were designed to meet the stringent requirements of current good manufacturing practices (cGMP) and 21 CFR Part 11-compliant environments. They also meet the requirements of global pharmacopeias – and our unparalleled implementation support ensures a turnkey solution.

Together, Thermo Scientific handheld Raman and NIR analyzers let you identify 90% of pharmaceutical compounds in seconds. With both instruments, you'll quickly and effectively identify any combination of materials in your manufacturing facility, from receipt to release.

With more than 650 GMP facility installations worldwide, we've successfully implemented our solutions into the top pharmaceutical companies and regulatory enforcement agencies around the globe – helping them to increase productivity and realize a rapid return on their investment.

“With TruScan, we save 600 hours per year. This is a great benefit for us.”

– Uwe Neitzel, Pfizer Manufacturing Deutschland GmbH

Your partner in deployment

We are more than a leading provider of portable analytical instruments. We are a true partner, delivering expertise and solutions to improve processes, reduce risk and costs, and achieve competitive advantage.

Our subject matter experts operate as partners in the deployment of your Thermo Scientific analyzers. With years of industry experience, proven implementation strategies and best practices, we help eliminate common implementation challenges to realize success in record time.

Prepared templates and documentation:

- IQ/OQ/PQ
- SOP Templates
- Statements of Compliance
- Supplier Quality Assessment

| Unit Installation | Development and Validation | Regulatory Review | Usage |
|-----------------------|--|---------------------------------|----------------------------|
| Execution of IQ/OQ/PQ | Computer Systems Validation <i>SyncServer, CFR 21.11 Review, and Change Controls Determined</i> | Specification Revision/Creation | Final Training |
| SOP Development | | QA Release | Releasing to Manufacturing |
| Project Charter | Method Development | Pharmacopeia Compliance | Additional Applications |
| Resource Allocation | Method Validation | QMS/ERES Vendor Completion | Return on Investment |
| | Documentation Assessment | | |

Application specialists along with staff scientists are available for technical consultation and supplier quality assessment review. We provide training that scales from method development and validation to general operator usage. Once up and running, you can count on us for customer support – anywhere in the world.



“The non-contact part is really key, as it allows containers to move more quickly through test zones.”

– Wolfgang Hermanns, a Thermo Fisher customer from A. Nattermann & Cie SmbH (Sanofi Group)

Reporting and documentation

The TruScan RM and microPHAZIR RX analyzers are fully networked and offer intuitive workflow that can be implemented quickly and easily into your unique production environment and both are designed for simple data sync using Ethernet or USB connections. These features preserve the integrity of data and help to comply with 21CFR Part11 guidelines.

Reports are also automatically generated and placed into a secure archive. During secondary review, managers can pull up reports individually or by batch. Formal sign off of these reports can be achieved manually or by pulling data from a cloud server and performing digital sign off using LIMS.



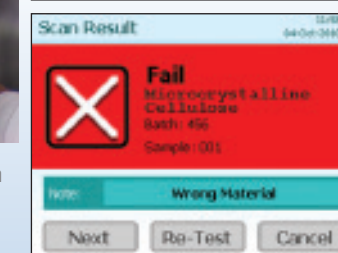
The technology

Using revolutionary algorithms that provide accurate, actionable Pass/Fail results, these rugged analyzers, engineered with attention to your requirements, perform nondestructive analysis directly through sealed packaging, eliminating the time and material waste associated with more traditional methods.

The specificity of Raman offers the ability to distinguish between small molecule compounds – which are typically strong Raman scatterers making the TruScan RM the analyzer of choice for this compound set. NIR reflectance measurements are well suited for larger molecules – making the microPHAZIR RX the ideal analyzer for large molecule compounds such as celluloses and other excipients used for secondary manufacturing.

Our services include:

- On-site execution of IQ/OQ/PQ
- On-site training
- Implementation consultation
- Regulatory consultation
- Pre and post installation support
- Remote certification
- 24/7/365 global customer support



Once a measurement is complete, the analyzers provide a clear Pass/Fail result within seconds.

The analyzers perform identification through sealed packaging to minimize the risk of contamination and exposure.



Customer service: comprehensive support

Our team of subject matter experts have successfully created implementation strategies for top pharmaceutical companies and regulatory agencies around the world. By working together, your analyzers will be up and running in no time.

NOTICE
ENTERING A
GMP REGULATED
AREA

Regulatory and market acceptance

Thermo Scientific portable solutions deliver specialized identification and analysis of raw materials for the highly regulated global pharmaceutical industry.

We've successfully implemented our solutions into the top pharmaceutical companies and regulatory enforcement agencies worldwide – enabling them to increase productivity and realize a rapid return on their investment.

- Implemented by 24 of the top 25 global pharmaceutical companies
- More than 650 GMP facility installations worldwide
- Used by more than 15 regulatory enforcement agencies for counterfeit screening

1 Readiness

- URD Evaluation
- DQ/IQ/OQ/PQ Documentation
- Project Team Orientation
- Project Timelines
- Technical Consultation (IT/EH&S)

2

Installation

- On-site IQ/OQ/PQ Execution
- Operational Training
- Champion Training
- Chemical Standards

3

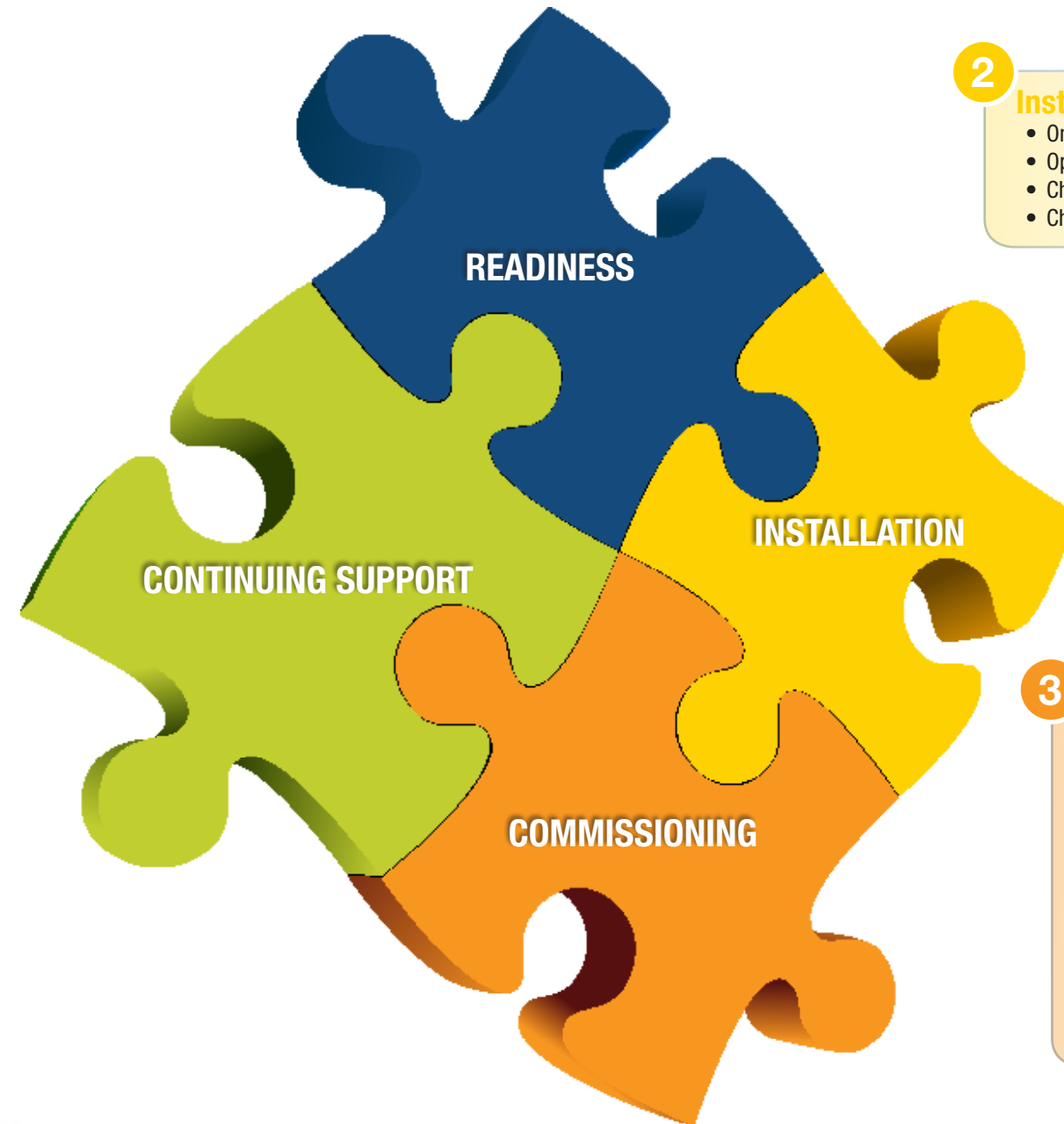
Commissioning

- Implementation
- Method Development and Validation Consultation
- SOP Templates
- Statements of Compliance
- Training Presentations
- Certification of Calibration
- Vendor Assessment (ERES and Quality Systems)
- Regulatory Compliance Consultation for USP, EP, and JP

4

Continuing Support

- 24/7/365 Support Line
- User Guides
- Maintenance Agreements
- Repair Services
- Customer Support Website
- Product Enhancements and Accessories
- Product Newsletter
- New Application Support
- Educational Seminars
- Company-specific Global Meetings
- Priority Regulatory Audit Support





Thermo Scientific TruScan RM and microPHAZIR RX analyzers are revolutionary instruments that can help you achieve compliance and realize a rapid return on investment throughout the manufacturing process.

Contact our experts today to learn more.



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