Materials Checking System Spectrum AssureID

Verifies the identity and quality of production materials

The revolutionary Spectrum™ AssureID™ materials checking system provides manufacturing QA functions with a rapid, un-ambiguous means of verifying the identity and quality of a pro-duction material, confirming suit-ability for use in the manufacturing process. QA can implement a mea-surement system that integrates easily into the manufacturing process and return business benefits shortly after delivery.

Rapid system implementation

AssureID mimics existing QA workflows, guiding developers through the development of simple, robust and reliable methods. New methods are developed, validated, built into method specific analysis work-flows, released by an authorized manager and then run by author-ized users. Implementation takes days rather than weeks or months,

reducing the method development burden and providing significant relief for busy QA functions.

Improves efficiencies throughout the manu-facturing process

Users with no scientific training can make measurements at all the important places and steps in the manufacturing process, from in-coming raw materials to final product inspection. Valuable analysts are released for other important work and the delays caused by getting samples to the laboratory and waiting for the results to return are eliminated.

Faster sample throughput

Sample preparation is minimal, often non-destructive and doesn't use solvents, allowing users to make measurements safely, without interfering with the manufacturing process. Data are automatically processed into results and rigor-ously follows the validated meth-odology. The system also provides tools for authorized analysts to quickly evaluate 'hold' or 'failed' samples and restart the process, if needed.

Key Benefits

➤ Choice of MIR, NIR or combined MIR/NIR systems

➤ Powerful chemometric engine eliminates the need for a chemometrician

➤ Designed to work the way QA works

➤ Reduces training requirements

➤ 21 CFR Part 11 technical compliance optional

PerkinElmer®

Maximizes business impact

AssureID speeds implementation, deployment and analysis allowing QA to test more frequently, avoiding expensive mistakes, reducing inventories, maximizing plant utilization and satisfying ever-increasing regulatory body requirements. AssureID is a major contributor to reducing costs. It releases hidden profits and provides the fastest way to maximize Return On Investment (ROI).

Proven measurement technology

Spectrum AssureID utilizes the proven Spectrum 100 and Spectrum 400 series FT-IR spectrometers to quickly generate high quality, sample specific 'fingerprints' of production materials that are compared to each other using a powerful chemometric engine. This simple spectroscopic technique makes it easy to move the analysis out of the laboratory and closer to the sample, for example into the loading dock area or onto the production floor. The spectrometer is available in Mid Infrared (MIR), and Near Infrared (NIR) plus dual range MIR/NIR versions allowing analysts to optimize technology for their specific problems. Both systems deliver impressive results from a

Figure 1. A powdered sample in its original glass-sampling jar is simply placed on top of the NIR sampling interface.

variety of sample types including solids, liquids, pastes, granules, and beads. Sampling is easy and convenient and there is usually no sample preparation required (Figure 1).

The AssureID software controlling the spectrometer is a 32-bit Windows® application, based on a single SQL database, with a familiar 'browser' style user interface (Figure 2). The software structure mimics the QA workflow with individual access controlled modules for developing methods, analyzing samples and reviewing results.

Compliance built-in from the very beginning

AssureID ES meets the stringent requirements of 21 CFR Part 11 and GAMP4. Before design work started an expert training company from within the pharmaceutical service industry rigorously trained the design team on 21 CFR Part 11 implementation. There is a secure, administrator defined Windows® and AssureID log-in process, with the ability to define user groups and permissions that reflect the QA workflow. For example, only a trained analyst might be allowed to validate a method or review results, whereas only the QA manager might be allowed to release a new

method for use. Compliance is intrinsic to the whole system with protected raw data, method audit trails and users forced to sign-off results, significantly reducing the cost of compliance.

Rapid method development

Once authorized developers are logged onto the Method Explorer module, they follow an intuitive sequential process to develop a method. The method development wizard (Figure 2) helps define the spectrometer conditions, sample type and sample presentation device and saves the method in the new methods repository. In this secure environment all subsequent changes to the method are recorded in an electronic audit trail.

The analyst then identifies multiple samples that fully define the potential quality limits of each material within the method. This involves gaining access to historical 'keep' samples and includes:

- Samples that are known to be well within specification
- Samples at the limits of specification
- Samples out of specification
- Samples of different materials, but ones that could be found in the same environment
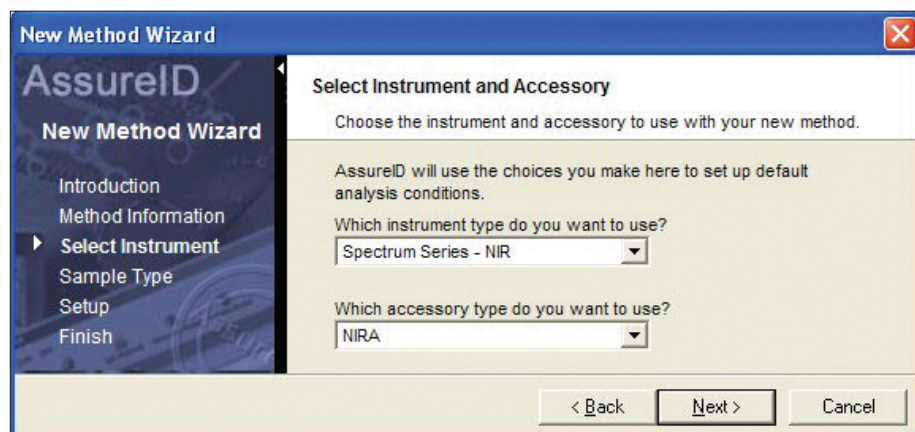

Figure 2. Method development wizard provides step-by-step guidance through method development making the process easier than ever before.

The samples are run on the spectrometer and the spectra immediately enter a secure data environment. They are saved in the database and then loaded into the method template (Figure 3).

Chemometrics without the chemometrician

AssureID then uses a powerful chemometric engine to model the method, comparing the fingerprints of all the spectra. This would normally require the services of a trained chemometrician, but not with AssureID. PerkinElmer's proprietary Scientist Inside™ replaces the trained chemometrician, but gets there much quicker, reducing the cost of retaining expensive expertise. Scientist Inside models the data in less than a minute and presents the developer with graphical and numerical knowledge of the success and boundaries of the model. Automatic troubleshooting routines then suggest ways the developer can improve the robustness of the method, making sure it is within required limits. Once satisfied, the developer validates the method by presenting the model with spectra of known specification. Start-to-finish, the process takes hours, not the weeks or months usually associated with developing new methods. AssureID's comparative technology can also be used to replace a slow, cumbersome quantitative method, satisfying QA requirements, more simply and at a lower cost.

Making it easy for users

AssureID is then able to turn the science into a simple method workflow that can be followed by non-scientific users, harmonizing procedures and reducing the training burden. It can be used for product identity or specification confirmation, quantitative analysis, and can even combine qualitative and quantitative analysis into a single workflow. A range of mathematical options based on similarity and distance metrics is available for identity confirmation, and both univariate and multivariate methods may be used in quantitative workflows. Standard workflows incorporate user messages, prompts, text entry boxes, timed requirements to run system suitability tests, and report templates. The workflows are generated using standard AssureID system tools and don't require any programming knowledge. The user interface is clear, uncluttered and easy to follow, eliminating mistakes and reducing the amount of support required from an analyst. More advanced workflows can incorporate SOPs, local languages or multimedia training materials making AssureID ideal for global manufacturing operations. The workflow user interface is written in HTML, so customers can customize the look and feel of the interface. QA managers can relax knowing users are forced to follow the validated methodology.

Releasing validated methods

Once the workflow is designed, the method can be submitted to an authorized manager for approval. It can then be released to the approved methods repository where authorized users can log-on to the Analyzer module and start generating results. When they have finished their work they are required to sign-off their results before logging off, generating an electronic signature within the secure database (Figure 4).
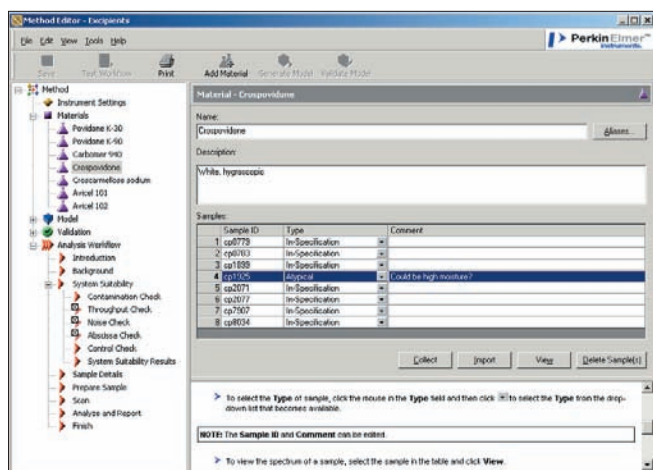

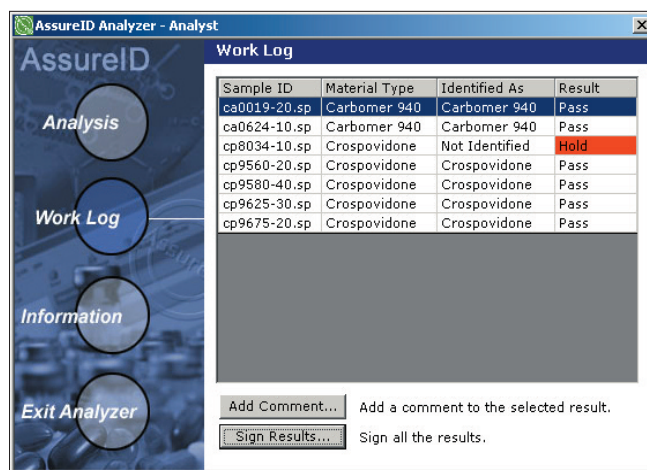*Figure 3.* Representative samples are loaded into a familiar browser-style template.

Figure 4. User's results session prior to sign-off with an electronic signature.

Problem solving

Samples deemed out-of-specification by the system are put on hold and forced to undergo an out-of-specification analysis by an authorized analyst, who reviews the hold samples by logging onto the Results Browser (Figure 5). AssureID provides tools to help the analyst solve the problem whether it is the result of a poor spectrum, an atypical sample or an incorrect specification.
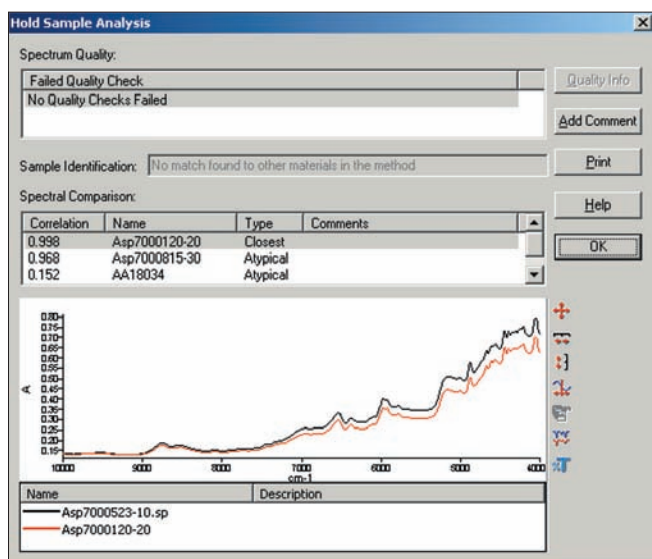
Improving business process

The Results Browser also allows authorized analysts and managers to query the database to help them make faster, more informed business decisions. Queries may involve using multiple selection criteria on any field in the database (Figure 6). For example, all the analyses performed by User A, on Material B, between May 1st and May 30th, which were out of specification.

Comprehensive built-in graphing tools allow comparisons and trends to be plotted on-screen or as part of a report. Intelligence gained may help identify a training requirement for a specific user or spot a material moving towards the edge of its specification, giving the QA team time to solve a problem before it occurs.
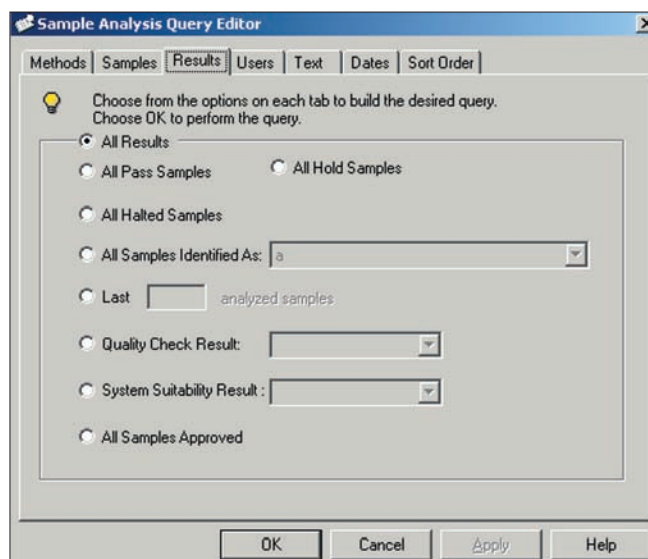

Figure 5. Comprehensive tools are provided to review and solve problems with 'hold' samples.

Figure 6. The Analysis query editor allows users to perform a query with multiple selection criteria on any field in the data base.

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