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Novinity Software announces the release of PAT toolkit™ Version 3.0 software for the FDA's Process Analytical Technology (PAT) initiative

Bozeman, Montana (October 5, 2006) – Novinity Software announced today the release of its version 3.0 for the PAT toolkit™. The software was designed specifically to implement the FDA's Process Analytical Technology initiative in pharmaceutical manufacturing. The company's third version builds on the software's data trending and analyzing features.

PAT toolkit was originally built over eight years ago for use in radiopharmaceutical production. The software allows manufacturers to observe their production processes as they occur and avoid potential problems before they happen. Particular focus has been made on designing the software to easily connect with industry standard equipment and platforms.

In commenting about the software's third release, Novinity's CEO Lance Tinseth said, "A consistent problem for our clients is the ongoing challenge of using different vendors' solutions and somehow making them connect and talk back and forth. Coupled with this is the headache of making sense of all this manufacturing data as it is happening or spending days or weeks after the fact approving the compiled paperwork. We're excited to offer PAT toolkit as a solution by providing a way to unite all this information together, regardless of the piece of equipment that produced it. By doing this in near real-time, clients have an instant snap-shot of the manufacturing process as it is occurring. This empowers pharmaceutical manufacturers to make better decisions, faster."

PAT toolkit can integrate with a variety of current PAT tools, such as NIR spectroscopy, via its Modeling feature. This works by process engineers building an ideal model of how their production process should look. The software then constantly compares incoming data to this model. This virtual "check-list" helps ensure there are no surprises at the end of a batch run. Over time an entire process can be brought online from raw materials to batch release.

PAT toolkit is also capable of leveraging multi-variate analysis (MVA) tools, to better predict product quality. In addition, third-party graphing and statistical analysis software can also be utilized to create powerful reports. All this is done in a 21 CFR Part 11 compliant manner. The software can be easily validated in a modular fashion with attention paid to only those areas changed via audit log or designated as a change control required component.

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By gathering, analyzing, and reporting on the data in real-time, manufacturers are able to easily spot potential weaknesses and refine their production methods. This helps not only with bettering the bottom line but also producing a safer pharmaceutical product.

About Novinity Software

Novinity Software (www.novinitysoftware.com) is an industry leader in Automated Data Management Systems (ADMS). Novinity was established to help their clients achieve higher levels of success by helping them to improve quality and productivity. Novinity's service and product focus is to provide maximum benefits while minimizing the costs of implementing software solutions.