

## Software Development Tools: The Key to a Solid Software Development Process

[Don Cunningham]

Waters is a manufacturer of instrumentation that's used for chemical analysis that's used in the food industry, pharmaceutical industry, a number of other industries.

So, the solution that we offer with Waters is really a system of systems. We have on one hand a database system that's connected to a number of other embedded instruments and systems that are used to do the chemical analysis.

The development process is interesting in that it's really put us in a situation where we had to do component-based development, where you have interfaces between various components. And we've had to look at our whole software development process differently because we can't just come out with a whole release of a system.

In terms of compliance, we need to adhere to FDA's good manufacturing guidelines and basically we need to have traceability from our own requirements down to the code that we actually generate.

...about 5 years ago Waters made a number of additional acquisitions overseas and essentially wound up with a situation where we had 4 separate software development groups. Basically we wanted to have a common platform for all of our tools in our systems that we're developing, so we needed to have a solution that allowed us to have collaboration across all sites, but added in a manner that everybody can't be available at the same time.

I was in a situation where I wanted to understand how effective our tools are that we're using now in terms of an audit and basically I requested or we had an opportunity for an audit, requested to be audited. And after about 15 minutes of spending with the auditor — he was just totally blown away on how effective the tools were in terms of addressing all of his audit questions. For example, "what are the requirements?" I brought up a DOORS document. "How is this implemented?" I brought up Change, showed him how it was implemented. "How was it tested?" I brought up Change again, showed him the test results associated with the change request. Do you want to see the code that was actually implemented, I could show him

that. It just took about 15 minutes and he saw that we had a rock solid process in place and he was very satisfied in terms of our compliance with our ISO process.

With the Rational tools, I just sit there at my desktop and I can just point to it, bring up the documents and it's all right there