



NIFDC

## Challenge

Find efficient and effective ways on a national level to test the quality and safety of China's food and medical products at various stages of the product life cycle.

# Safeguarding China's nearly 1.5 billion citizens

The National Institutes for Food and Drug Control look to statistics to ensure that product safety standards are met

When the Chinese government tasks one of its state agencies with keeping citizens safe, scientists turn to statistics. The work is too important to leave it to chance – or even more traditional research methods that require a degree of guesswork – says De-jiang Tan, Deputy Director of Pharmacology at the National Institutes for Food and Drug Control (NIFDC).

The life sciences have historically suffered from a lack of reproducibility when it comes to experimentation. Laboratory conditions can be imprecise, meaning that one lab's experimental results may be difficult for another lab to recreate. But such replications are essential, particularly when it comes to food and medical products that must pass several levels of safety- and quality-related scrutiny; manufacturers must prove to regulatory agencies like NIFDC that the science behind their products is sound.

Tan explains that the NIFDC is responsible, on a national level, for ensuring the safety of four areas: food, cosmetics, pharmaceutical and biological products, and medical devices. And as one of the largest subsidiaries of the Chinese Food and Drug Administration, the NIFDC is also responsible for developing and distributing guidelines and other standards of compliance. The scope of this mission is enormous, and the responsibility is unequaled: The NIFDC tests more than 13,000 batches of pharmaceutical drugs alone each year and distributes around 4,000 reference standards. That's why the organization relies on statistical methods to help NIFDC scientists and administrators make timely, well-informed decisions about the products they allow to be sold within the country.

## Shifting toward scientific methods backed by statistics

Statistical methods help to reduce the gap between traditional standards for scientific replication and what is now required in regard to proof of compliance. Fortunately, the NIFDC was an early adopter of this kind of thinking. In the agency's formative decades, former Director of Pharmacology Dr. Yu-jun Xu was an outspoken advocate of biostatistics, promoting the use of analytical methods in regulatory monitoring at the national level. By the mid-1970s, NIFDC General Director Hai-jun Zhou – also a pharmacologist – was carrying on Xu's legacy. He began to study and standardize the way statistical methods were applied across the department; bioassay and other biostatistical methods soon became a requirement.

A reliance on data continues to factor into the NIFDC's core philosophy, one that Tan himself continues to foster. "This is big – applying statistics to save lives," says Tan. He explains that the NIFDC has seen quantifiable improvements since it began encouraging the use of statistical methods by its scientists; a reduction in the time it takes to run experiments, for example, has resulted in widespread efficiencies and better, more reliable results.

And the public is taking notice of these successes. Tan explains that the people of China want to know that the food they eat, the drugs they take, the cosmetics they use and the medical devices they rely on are safe. "The public needs to have confidence in what we say," says Tan. "And the fact that we use statistics to make decisions is comforting to people."



The more correlations we find in our work, the more scientific our decision-making process becomes. JMP is helping us to do better science.

De-jiang Tan, Deputy Director of Pharmacology



## Scientists prioritize investigations by assessing risk to public safety

With such an ambitious mission, the Beijing-based organization's more than 800 employees must prioritize how they spend their time. That means products bearing the highest risk to public safety will be scrutinized at a national level, while lower-risk products will be handled at the provincial or local level. Injectable medicines are a prime example of a high-risk product that NIFDC scientists would examine most closely.

For example, scientific investigators from the NIFDC responded to the report of a possible immunoglobulin injection-related death. Tan's unit is often the first call with this kind of incident. "We had to get in there and investigate," he said. In this instance, an NIFDC investigation found that the non-compliant product in question had been the source of a fatal protein denaturation.

As with injectable-related incidents, some investigations are motivated as the result of suspicious death or sickness. But the vast majority of the NIFDC's inspections are conducted on routine samples sent in by manufacturers seeking regulatory approval, following their own internal quality control validation. And others are proactive on the part of NIFDC, where the organization conducts random or spot sampling evaluations.

## Data visualization features in JMP® make statistical methods accessible to scientists

"We are scientists, not statisticians," says Tan, who adds that even still, scientists need statistics to do their jobs properly. Laboratory testing is a central part of the NIFDC's work. And while traditional best practices for lab-based experimentation once involved a degree of guesswork and intuition, the field is shifting toward a more analytics-powered framework. Now, statistical analyses guide experimentation and testing in order to boost the rigor of experimental results.

"JMP is my most loved statistical software," Tan says, noting that he has used other statistical analysis tools in his career, though none as easy to use as JMP. Before buying JMP, the NIFDC considered many statistical packages. In the evaluation process, two factors stood out about JMP, he says. First, because it is so visual, JMP makes it easy for scientists to explore data and employ the statistical analyses they need, even when they haven't had any formal training in statistics. And second, Tan says that as a SAS® product, JMP is reliable; there is no concern about its quality.

Now one of many JMP users at NIFDC, Tan is pleased to see other scientists working with statistics through data visualization. Results backed by statistics are more reliable – and the science is more reproducible, he says. That is, statistics is driving experiments that are more easily repeated, reviewed and verified. Moreover, these higher-quality outcomes are being achieved in a fraction of the time previously required for research processes. That means the NIFDC is processing more investigations and regulatory submissions and doing so faster than ever before. "Statistics are super important to us. The more correlations we find in our work, the more scientific our decision-making process becomes," he says. "JMP is helping us to do better science."

### The NIFDC's Mission

- To monitor safety and quality compliance by performing inspections and quality tests of food and medical products, as well as the facilities that supply them.
- To monitor the performance of medical product testing laboratories according to standards set forth in the proficiency testing provider's scheme.
- To examine imported products and certify that they are compliant with national quality standards.
- Perform technical verifications and supervise the registration process.
- Research, prepare, calibrate, distribute and manage national regulatory standards for food and medical products.

## Solution

NIFDC scientists use statistical methods in JMP to make more scientific, data-driven regulatory decisions to guarantee the safety of food and medical products across China. JMP is integral in the NIFDC's extended efforts to perform comparative evaluations of quality and proficiency parameters for product testing laboratories across China.

## Results

Chinese citizens have increased confidence in the safety of the food and medical products they consume.

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