A chemist with a passion for technology

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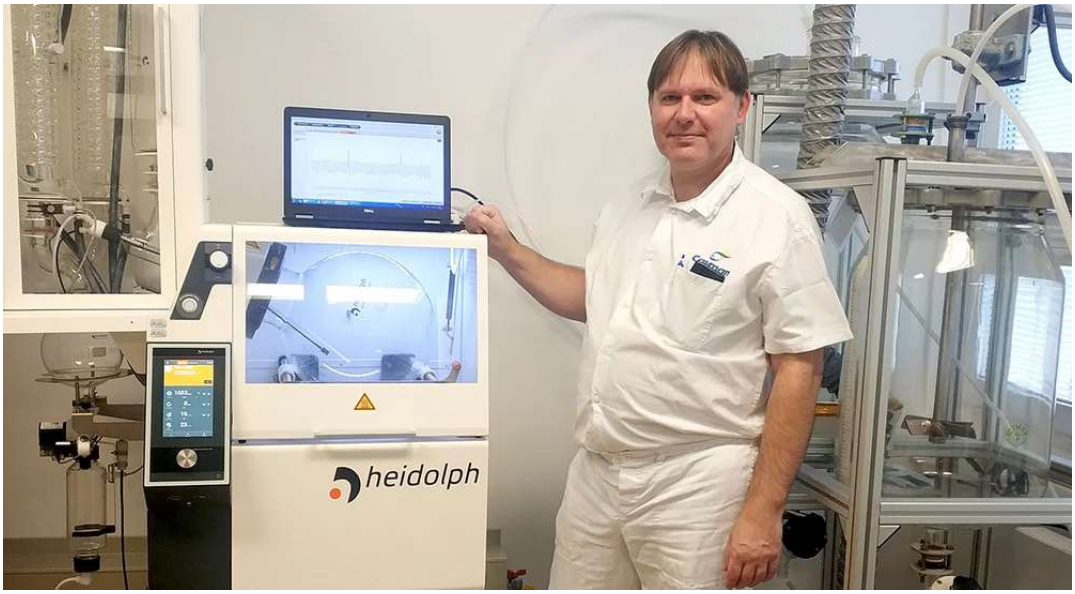
They say that you learn by making mistakes. But there are areas of human activity where you simply cannot afford them. One of them is the pharmaceutical industry. "That's also why in the United States, around thirty years ago, they invented the concept of qualifications and validations to minimize the threat to the health and lives of patients," explains Jiří Kočí, who is in charge of qualifications at Cayman Pharma. Together with validation technicians and other colleagues from the technical department, they strive to ensure that their company produces its products, medicinal substances, in one hundred percent quality. "Any new product, but also any innovation, for example of a production process, must first go through us."



***Jiří Kočí** is a qualification technician at the pharmaceutical company Cayman Pharma and, in addition to qualifications, he also takes care of clean rooms. He is one of five employees of the technical department, which ensures qualifications, validations, but also, for example, environmental matters. The company is an international leader among pharmaceutical companies producing prostaglandin-based active substances.*

How does it work in practice? For example, when you introduce a new product to the market.

We review innovations and changes far more often than we introduce new products. But we can take this as a model situation. The first phase takes place in the research department. When our researchers are sure of the product's properties and that we can repeatedly produce it with the same quality, they enter the stage of qualification - selecting machinery or verifying that the existing one is capable of ensuring problem-free production.

So you actually step up to the machine?

Yes, my job is to test and approve production equipment before it is used in real production. Simply put, if, for example, the SOP (*standard operating procedure – a set of regulations that operators follow during routine production, editor's note*) suggests conducting a reaction at a temperature of 55 to 60 degrees Celsius and we do not have the equipment in question, a full qualification is needed, when I participate in the creation of the specification of user requirements for the device, I check the technical offer on the market and finally the suitability of the chosen solution. After purchasing new equipment, I verify its proper installation at the site of future use, and finally test the equipment's ability to reach the intended operating range for the desired temperature, i.e., whether it can handle that 55 to 60 degrees Celsius.

Multidisciplinary orientation is an advantage

So you actually have to be not only a chemist, but also have technical knowledge.

You know, that's what I like best about my current job. Even though I'm a trained chemist and I've been involved in chemistry all my life, I've always been more attracted to technology, especially computers. And in my current position I can apply both.

Moreover, it is a position that you will probably find difficult to learn in school, the greatest teacher is practice, isn't that right?

Absolutely. In almost thirty years, I went through production in our company from the position of operator to foreman to the current technical department. I like both chemistry and technology and I have no problem learning something and continuing my education. In the field of qualifications, you cannot do without it. The regulations are constantly getting stricter and the technology is also developing very fast. In the beginning, I dealt with qualifications at the same time as my master position, today it would be impossible to manage.

Now let's move on to the validations that your colleague is in charge of and are inextricably linked to qualifications.

Once the qualifications have taken place, the next step is the validation of the manufacturing process. Production performed at the limits is tested to verify that even under the limit conditions you will produce a batch of the desired quality. Validation of device cleaning is also an essential part of the validation work.

Does "dishwashing" also have to be validated?

It is just as important as validating your own manufacturing process. You must be sure that the proposed procedure for washing the production equipment guarantees that you do not contaminate the next production batch with residues from the previous one.

> If you simply enjoy and are interested in your work, no one has to force you to learn new things.

How often do these processes take place in your company?

As I already mentioned, we don't introduce new products that often, but there are a lot of partial changes, on average one a month, and they can only be implemented on the basis of prior qualification and validation. In addition to changes, we are obliged to revalidate all our final stages of production once a year, i.e. to verify that we can still produce our product with the same quality.

Well, that's probably going to give your department a hard time. How does the electronicization of data, which has been ongoing in your company for a long time, help you?

We used to work with paper documents, today the documentation is in computers, which helps us a lot, but our goal is much greater digitization.

As if, for example, a person no longer tests and validates, but a machine-robot?

Nejste tak daleko od pravdy. Když dnes vyrábíte nějakou šarži, musíte dodržet institut kontrolující osoby. V praxi to znamená, že jeden pracovník výrobní činnost provádí a druhý jej zejména v kritických částech postupu kontroluje. Průběh zaznamenávají a podepisují v operačním listu. V budoucnu by tou „kontrolující osobou" měl být skutečně software, který nejenže může navádět operátora ke správné činnosti a zaznamenávat naměřená data, ale reálné vstupy okamžitě porovnává s předpokládaným průběhem. Vznikne tak elektronický operační list – záznam o výrobě, který je hůře falzifikovatelný než papírový. To je budoucnost naší profese. Ve světě už tato praxe existuje, záleží pouze na finančním zázemí, jak rychle se bude aplikovat u nás.

S Jiřím Kočím hovořila Jana Jenšíková
Foto: archiv Cayman Pharma

Kvalifikace – činnost prokazující, že zařízení nebo pomocné systémy jsou ve shodě s požadavky, jejich použití je vhodné pro daný účel, jsou správně instalovány, správně pracují a jejich činnost skutečně vede k očekávaným výsledkům.

Validace – získání důkazu ve formě dokumentace, jenž poskytuje vysoký stupeň jistoty, že určitý proces bude trvale poskytovat produkt odpovídající předem určené specifikaci.

Systém řízení kvality při výrobě farmaceutických ingrediencí a léčiv se nazývá správná výrobní praxe (SVP). Kvalifikace a validace jsou jejími základními nástroji.

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