MEXICO BUSINESS NEWS

COMPANY REPORT

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Powder Handling Complexity Resolved

Q: What role do Dec's solutions play in the pharmaceutical and chemical industries?

A: Dec is a family business founded more than 30 years ago. We are dedicated to safe powder handling through containment applications. Dec develops its own technologies, among them the Power Transfer System (PTS), which uses both vacuum and pressure to move powders as if they were liquids. This eliminates the need for gravity charging, making multifloor processes a thing of the past. Thanks to this development, we have been able to grow from the chemical industry to the pharmaceutical sector as PTS allows mixing, dosing and sampling. It allows diverse filling methods as we have improved the system to handle large or small powder quantities.

Product development for pharma is one of our strengths. However, manufacturing can be more challenging. Dec's work begins at laboratories, especially with ingredient mixing, which is normally done through sophisticated machines. It is here where we try to propose a higher industrialization of facilities by introducing our technology, which is targeted to improve efficiency and safety.

Q: How representative is the pharmaceutical industry for Dec's operations?

A: I would equally divide our work with the pharmaceutical industry in two areas. The first is API production. This is the area where Dec's solutions are predominant and where we have developed technology to enable strict conditions of operation due to manufacturing complexity, as companies handle extremely dust-explosive and hazardous materials. Dec also provides solutions for formulation and primary packaging processes. The pharmaceutical industry represents 60-70 percent of our activities.

Q: How do Dec's business lines contribute to growing your added value?

A: We have four main divisions. The first is technology, where we develop unique products that respond to advanced needs. The second division is engineering, where we integrate different technologies into a project. We do not just sell a machine, we sell a solution. The third division is consulting, where we advise our customers and communicate our new solutions to the potential market. The last division is services, where we offer global customer field support to make sure operations run smoothly.

Q: How have you adapted your technology to the Mexican pharmaceutical industry?

A: Just as in other countries, our solutions have been very well received in Mexico. We always make sure to comply with each country's requirements and follow the principles of protecting people and the environment. Our company is committed to each regulatory system and we work on building effective solutions through constant improvement.

Q: What success case can you share in handling contained powders in the pharmaceutical industry?

A: One of our multinational clients has a facility in Central America and they faced regulation changes that they had to comply with. To do so, they basically needed to change their facilities to ensure distancing of people and goods, as there was no way to comply with the regulation with their current spaces. Dec was able to provide a solution to keep the company running by adapting part of the building.

Q: Which of your solutions or products has had the most impact in the pharma industry?

A: Our core business has always been handling powder. This is a very complex task for every facility and companies mostly prefer to work with liquids or solids. We have been able to introduce safe powder transfer that moves from one operation to the next without failure. This has revolutionized the industry because it closes an operation line as it interconnects the entire pharmacochemical process chain.

> "We have been able to introduce safe powder transfer that moves from one operation to the next without failure"

Q: What potential do you see for powder handling in Mexico?

A: API production has moved away from Western countries for cost reduction reasons, which is why 80 percent of it is in Asia. Due to the COVID-19 disruptions, the industry saw production lines threatened by the lack of supplies. Western countries have begun to look for ways to bring API manufacturing back, which is an opportunity for Mexico for two reasons. First, the country is right next to the US. Second, the country has built a strong network of pharmaceutical companies. Mexico has all the elements to increase its API production.

Q: What are Dec's expansion plans in Mexico?

A: We have successfully covered the handling of raw materials for the chemical and pharmacochemical industry. The next step is to reach our customers and use this technology properly. Dec will be working on constant improvement, such as in filling processes. We are also interested in entering vaccine handling and other liquid elements. Vaccines need to be kept at very low temperatures and the industry is looking for different ways to move vaccines. Companies have turned to powder management as an option, to combine it with liquid prior to injection. Dec is developing these packing options for vaccines to make access less complex or less dependent on strict cold chains.

Educating the industry is another goal. We have become a leading actor in the market because we develop innovation for the future. We are always ahead of the curve in terms of understanding the problems associated with pharmaceutical or chemical manufacturing. What is important now is to educate customers and authorities on innovative technologies. This continues to lead us to promote these solutions which, in the end, will increase the growth and productivity of other companies.

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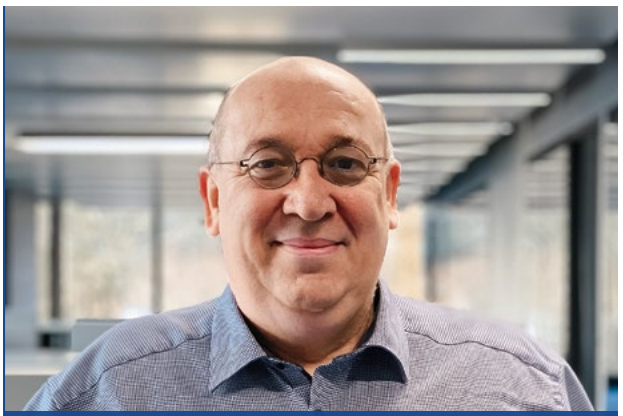

Henry Ederle

Area Sales Manager of the Industrial Division | **Borer Chemie**

Massimo Desole

Director of the Industrial Division | **Borer Chemie**

Precise Cleaning Engineering for Production Lines

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Q: What is Borer Chemie's major contribution to its different clients?

HE: Borer has four large divisions. The first is Borer Medical, which tackles cleaning and disinfection, mainly for hospital facilities and surgical instruments. The second division, which is the one we lead, is Borer Industry and is focused on production of medical technology, including production of chambers, medical devices and medical instruments, parts and other support tools. Third is Borer Life Sciences, which offers cleaning services for laboratories and pharmaceutical production. Fourth is Borer Hygiene, which experienced 1,000 percent growth against 2019 given its focus on professional hand and surface disinfectants. This was one of our most popular services during the pandemic.

Our vertical, Borer Industry, is mainly focused on high-precision cleaning, before and after reaching the final product stage. Our in-demand services are cleaning agents for precision parts cleaning and ultrasonic cleaning and residue-free cleaning processes for many industrial manufacturing process. We work with aqueous cleaning techniques. Almost 80 percent of our cleaning applications use ultrasonic cleaning equipment. We have a very high degree of cleaning precision, which is needed to deliver final products in the tool industry (prior to PVD-coating), medical technology and ophthalmic industry sectors.

MD: One of our key customer segments is cleaning and passivation of medical instruments and implants. We also work with injection molds, which are used for medical injection parts. For the latter, we see a very big market in Mexico. We train our worldwide distributors and customers regularly, according to our R&D cleaning studies. We have approximately 15 different detergents in the MT Line of our product portfolio, where MT stands for medical technology . Borer also provides support documents to help for the process of qualification and validation.

Q: How does Borer approach new clients in such a niche market?

HE: We work through partners. However, we also make yearly visits to our partners and customers abroad. The main goal of these visits is to advise them on how to optimize our technology. COVID-19 has made this process more difficult, although in some markets, we can still safely reach more customers. Before we enter a market, it takes a number of years to find the customers we want to work with, so normally this is a slow process.

Our treatments are so specialized that we work with niche clients. Therefore, normally we reach them through word of mouth or through personal research of companies we think will require these services. We work alongside these companies to create a process that fits their cleaning line, instead of disrupting their processes. Our goal is to optimize their processes by adapting our solutions.

MD: We work on business research and develop close customer contacts to understand specific applications. For Borer Chemie, our work goes beyond adapting our products; it involves a lot of engineering to fully meet the needs of the companies we work with. We are not selling a product; we are selling a process.

Dec: Powder Handling Innovation for Multisector Processes

With over 30 years of experience, Switzerland's Dietrich Engineering Consultants (Dec) offers innovative solutions in powder handling and process containment, including transfer, micronizing, filling/emptying, sampling, blending, dosing, aseptic solutions, milling, isolators and advanced cleaning (CIP/SIP) features. Its in-house technology development has made it the leading global provider of powder handling and process containment systems for the pharmaceutical, chemical, food and cosmetics industries.

Pharmaceutical and Chemical Powder Micronization

Powder micronization is a process that reduces the particle size of a material, which is often performed using fluid mechanical mills. These mills, however, face common pitfalls, including cleaning issues and heat generation. Mechanical mills also have a high-particle lower-size limit of 40 µm. These problems can be controlled with Dec's MC MC DecJet® fluid energy mills.

Dec is a pioneer in spiral jet milling that has addressed particle-size reduction by collision since the 1960s. The company continuously developed its technology over the next decades, leading to today's high-performance fourth-generation jet mills that are now used in many industries, notably in the pharmaceutical and chemical sectors.

Mechanical mills are usually the first technologies considered by pharmaceuticals, cosmetics or sanitary materials manufacturers when evaluating particle-size reduction.

Well-designed, high-speed mechanical mills can grind friable materials to a low-micron size.

Dec's new fourth-generation MC DecJet® range, developed with Computational Fluid Dynamics (CFD) analysis, is revolutionizing existing micronizing procedures through improved geometry of the grinding chambers and ring integrated nozzles, which allow companies to obtain powders with very low particle-size distribution (PSD) of about 1 µm (Gaussian curve).

Moreover, micronizing isolators provide full containment of highly active and/or sterile compounds offering both operator and product protection. The MC DecJet® micronizing and containment range (from MC DecJet® 30 to 400) is the perfect union of Dec's years of experience as users and providers of micronizing and containment technologies.

Extensive in-house testing facilities have allowed Dec to test both nontoxic compounds using standard open-range jet mill systems as well as highly toxic compounds with its state-of-the-art high containment micronizing isolation system with fully automated control, gravimetric feeding and a dedicated air handling system that is capable of achieving specific temperatures and relative humidity requirements.

PTS: the Swiss Original Powder Transfer System

As a specialist in powder handling, Dec's registered technology PTS Powder Transfer System® challenges conventional processes by using both vacuum and pressure to move powders as if they were liquids. This eliminates the need for gravity charging and makes multi-floor processes a thing of the past. While there are many vacuum conveyors on the market, Dec's system is unrivalled due to its unique filtration concept with a flat filter membrane that makes it the only vacuum dense-phase system available that functions at optimum levels during each cycle, differentiating it from the run-of-the-mill systems on the market.

"Thanks to this development, we have been able to grow from the chemical industry to the pharmaceutical sector as PTS allows mixing, dosing and sampling. It allows diverse filling methods as we have improved the system to handle large or small powder quantities," explains Frederic Dietrich, CEO of Dec.

The PTS is ideal for transferring highly explosive powders and toxic and hygroscopic materials. One of its major advantages is that it separates the air from the powder, keeping the receiving vessel inert during the charging operation. This makes it possible to safely charge powder into a reactor that contains solvents or is pressurized without risking explosions.

As a solution for the pharmaceutical, chemical, food and cosmetics industries, PTS encompasses a wide range of applications:

+ Standard and high containment filling and discharging: PTS provides a safe solution for filling or emptying big bags and drums.
+ Small quantity dosing: Accurate and repetitive volumetric dosing of small quantities of powder ranging from 1mg to 100g.
+ Single and multiple reactor charging: Safe reliable vessel charging as the oxygen is removed from the powder before entering into the process.

+ Blending: PTS Batchmixer® for fully contained homogeneous powder blending.
+ Filling and packaging facilities: Supported by the Continuous Liner System for optimized GMP compliant packaging, the PTS and the DosiValve® system allow for any equipment discharging and precise dosing into drums and containers.

Blending/Mixing

"Dec's work begins at laboratories, especially with ingredient mixing, which is normally done through sophisticated machines," says Dietrich. "It is here where we try to propose a higher industrialization of facilities by introducing our technology, which is targeted to improve efficiency and safety."

The sophistication and complexity of mixing powders depends on the cohesiveness of the materials, the differences in bulk density and particle size and the selection of an appropriate mixer. Thus, achieving a satisfying balance between mixing rate and segregation might be a significant challenge.

As a result, Dec has developed PTS Batchmixer® based on groundbreaking PTS technology to mix powders in a fully contained way without using any rotating or moving parts. Dec's solutions can be classified according to the mixing mechanism:

+ Diffusive mixing, which occurs when particles roll down a sloping surface.
+ Shear mixing, which occurs when slip zones are established in a powder.
+ Convective mixing, which occurs when circulation patterns are set up inside a bulk powder mass.

Dec's Industry Reach

Dec's divisions enable the company to deliver complex solutions. The first division, technology, allows the company to "develop unique products that respond to advanced needs," says Dietrich. The second division is engineering, which allows Dec to integrate different technologies into a project. "We do not just sell a machine; we sell a solution," says Dietrich. The third division is consulting, in which Dec advises customers and communicates its new solutions. The final division is services to offer global customer field support that ensures operations run smoothly.

Dec's customized solutions can be tailored to specific customer requirements in the chemical, pharmaceutical, cosmetics, food or special materials industries. Depending on the sector, Dec has introduced numerous solutions:

Chemicals: Fine chemicals, agrochemicals, specialty polymers, adhesives and dyes and pigments handling

Pharmaceutical APIs: Reactor charging, pack-off, dispensing, blending, sampling, micronization and contained bulk handling.

Pharmaceutical Secondary Manufacturing: Oral Solid Dosage (OSD), Orally Disintegrating Tablets (ODT), Intravenous Therapy (IV), Dry Powder Inhalers (DPI) and sterile manufacturing.

Food: cGMP compliant handling and processing systems.

Cosmetics: Powder handling, micronizing and blending.

Materials Processing: Batteries manufacturing, automotive industry, nuclear and explosive powders.

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The Impact of Pharmaceutical Services on the Health System

Deyanira **Chiñas**

Commercial Director | T5DC

The role of the pharmaceutical professional in Mexico has been confused, and in the best of cases badly misinterpreted, since the generalized idea has been that the "pharmacist" is the person you find behind the counter at a pharmacy. Nothing could be further from the truth; the staff that today takes care of customers in a pharmacy receive very basic training in the operation of the pharmacy. They can basically identify where the medications are located; at best they can identify the general function of the different drugs and the presentations they are available in.

However, the COVID-19 pandemic has highlighted more than ever the role of pharmaceutical professionals on all fronts of the health industry, forcing a revaluation of the position, now identified as a professional activity of great importance and a high added value. In Mexico, just in January 2020, the pharmacist professional was recognized as a fundamental part of the health team by the General Health Law that governs our country.

Today pharmacists are participating:

- in the development of the vaccines and drugs that can put an end to this pandemic, including their design, production, and quality control, that must confirm that they are safe, pure, and effective;
- in the development of therapies with alternative medications that allow people already infected to come out ahead;
- in the design and correct application of medical devices that are necessary for the vigilance and therapy of the patient;
- in the execution of pre-clinical and clinical studies that will ensure if medications and vaccines will be effective;
- in the good use, dispensation and management of medications in hospitals and communities, hand in hand with treating physicians;
- in the pharmacovigilance and technovigilance of all elements used in the therapies, which allow us to clearly identify undesirable and adverse effects and avoid them;
- in the correct management of medications in distribution chains and storage, to ensure they arrive in the best possible condition for the patients use.

To work correctly in all endeavors, not only for the treatment of COVID-19 but for all diseases, including cancer and chronic degenerative diseases, pharmacists must be prepared; they must train, study, update their skills and innovate so that they can contribute the benefits that our society requires in the scope of chemical-pharmaceutical science and as members among the health professionals who integrate the country's health team.

A group of expert colleagues who form part of the National College of Pharmaceutical Biological Chemists of Mexico A.C. (CNQFBM A.C.) have recently written a work called The Book of Pharmaceutical Services. In this document they have compiled information that is considered basic and fundamental for the correct and complete training of the professional pharmacist for the tasks they will need carry out in the different fields of health promotion.

The current definition of the pharmaceutical services established by the International Pharmaceutical Federation (FIP) is: the set of activities directed to the promotion, protection, and recuperation of health both for the individual as well as for

society, using medications as an essential supply, searching to guarantee the access as well as the rational use of them. This set of actions includes the research, development and production of medications and health supplies, for their selection, as well as programming, acquisition, distribution, dispensation, and quality guarantee of products and services, and follow-up and evaluation of their use.

Each continent, country and region will establish the reach of pharmaceutical services in accordance with their current needs and surely this will be updated according to breakthroughs, modifications and extraordinary needs that arise in each case; however, in Mexico, the following chapters of the proposed book have been considered

Chapter 1. Pharmaceutical services

Chapter 2. Normativity and regulatory framework for pharmacies

Chapter 3. Profile of the pharmaceutical professional

Chapter 4. Current situation of the pharmaceutical services in Mexico

Chapter 5. Pharmaceutical services safe and effective: ergonomic and design contributions

Chapter 6. Pharmaceutical attention

Chapter 7. Administrative process of the pharmacy: the role of pharmacists in hospital administration.

Chapter 8. Pharmacotherapeutic follow-up

Chapter 9. Impact and importance of the dispensation as strategy and fundamental axis for the rational use of medications in the sanitary health system

Chapter 10. Conciliation of medications

Chapter 11. Sanitary education: concepts and boarding techniques

Chapter 12. Pharmacovigilance

Chapter 13. Design and construction of indicators

Chapter 14. Relationship between pharmacological research and clinical in the generation of new evidence

Chapter 15. Medications information search

This work is destined to modify substantially the criteria with which the role of the pharmaceutical professional has been identified historically; and, of course, ,the impact of the pharmacist's knowledge will be re-valued because today, they can collaborate directly alongside treating physicians in therapies and treatments, participating and monitoring the best pharmacotherapeutic proposal for each patient, as well as participating directly in the creation and follow-up of an integral plan for health promotion.

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The Importance and Impact of The Cleaning Process

Deyanira Chiñas

Commercial Director | T5DC

Cleaning has always represented a big challenge in the pharma industry. Regrettable events that have led to the loss of human lives have forced us to remember that avoiding cross contamination by every means is always a necessity in the industry.

It is an absolute that no risk of any type can be allowed because, instead of solving health issues, we would be generating events that can cost lives. Just remember the case of the dirty 200kg containers used to package tons of a raw material, that were literally shipped worldwide. These turned out to be contaminated with residue from petroleum derivatives because the cleaning of the containers was not assured.

It took several cases like this before the world's regulatory authorities established basic rules to guarantee that medications manufactured with raw materials and materials that are used to manufacture and package medicines are safe, pure and effective.

It is for this general reason that regulatory agencies expect manufacturers to develop and validate an integral and complete general cleaning program; in fact, the cleaning process is considered a critical system within the industry, which is why the risk of contamination, residue carryover from products, and any type of cross-contamination must be monitored, controlled and minimized to safeguard the security of patients and the quality of the product. An integral part of an effective cleaning program is using a risk-based approach, both for the design and for the good management of the cleaning validation; at the end of the day, the most important factor is to design cleaning programs that are compatible and effective. We must not lose sight of the fact that validated cleaning is a requirement that applies to these industries: biotechnology, biological, pharmaceutical, diagnostics, nutraceuticals, medical devices and even cosmetics.

The main purpose of cleaning validation is to prove the effectiveness and reproducibility of the cleaning process for production equipment and/or related parts, to prevent the cross-contamination and adulteration of medications or biological products, whether by another active substance, chemical agent, or unwanted compounds (for example, active ingredients, residues, excipients or detergents), or from microbiological contamination. This includes establishing criteria to reduce risk in patients by producing medications that meet the criteria of quality: that they are safe, pure and effective.

The processes of cleaning and their validation have evolved so much that, today, a broad number of segments have incorporated these processes, including:

+ Research and development, since they establish the manufacturing processes and, therefore the cleaning of equipment and areas, as well as defining the chemical agents for cleaning.
+ Toxicology, since there are substances with high pharmacological activity, which is why it is imperative to determine the limits of allowed exposure and acceptable daily exposure (ADE).
+ Engineering and maintenance, since they are heavily involved in the design of the equipment and their respective maintenance and cleaning.

- Production and validation, which are the ones that operate the equipment, mount and disassemble pieces, solve operational and maintenance problems, as well as execute tests and report the validation protocols.
- Control and quality assurance, which are the groups that perform samplings, laboratory studies, analytical method developments, and monitor the compliance of the GMPs.

The guides and regulations of reference used have been developed by countries and advanced international organizations, such as:

- CHP&FBI Guidance–Canada
- EMA–European Union (European Medicine Agency)
- FDA (Food and Drug Administration–USA)
- ICH (International Conference of Harmonization)
- PIC/S (Pharmaceutical Inspection Cooperation/Scheme)
- OMS (World Health Organization)

Likewise, there are existing pharmaceutical documents and guides developed by experts within the pharma industry, such as APIC, ASME, BPE, ASTM (several), ISO 13408, ISPE and PDA.

The most important aspect that the manufacturers of medications need to establish is the limits of residue acceptance, and the criteria must be defined based on the type of substance; that is to say, if the residue comes from highly dangerous compounds, meaning compounds with a low daily exposure acceptance (ADE), for example =<10 mcg/day, a specific analytical method must be used to quantify the residue (HPLC) and to establish the maximum allowed carryover (MAC). The best examples are psychotropics and oncological medications.

In the case of non-hazardous compounds, these refer to compounds with an ADE >= 100 mg/day; in these cases, the PDE corresponds to a dose of a specific substance that is unlikely to cause any adverse effects to a person is that individual is exposed every day of his life to the these expressed doses or less. In the case of a substance that is going to be cleaned in the manufacturing equipment, then it's possible to consider the use of non-specific analytical methods to be used for residue quantification, as is the case of the Total Organic Carbon (TOC), and thus establish a safety limit.

Frequently the actors in the pharma industry ask, what are the references that indicate that a non-specific analytical method could be used to determine the residue? Here, we have included all of the official and guild references that exist in that regard; however, the most important issue is to develop the scientific rationale that supports the decisions made to use non-specific analytical methods.

We have shared in different forums our successful experiences running correlation tests, where an active substance is quantified by HPLC and TOC in parallel; if the results demonstrate that similar results are obtained with both analytical methods, with statistical support — evaluated by experts in pharmaceutical statistics — then they already have in hand the necessary "scientific rationale" required to demonstrate before any regulatory agency and justify the use of non-specific analytical methods for cleaning validation.

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Total Organic Carbon Solutions for the Life Sciences Industry

Pharmaceutical-grade water systems and process equipment require Total Organic Carbon (TOC) and conductivity analysis to detect chemical impurities. When choosing TOC technology, it is important to ensure that it is fit for purpose and meets user and regulatory requirements for accuracy, precision, specificity, quantitative data and other important validation requirements. Strict compliance is the foundation of SUEZ's Sievers M500 Total Organic Carbon (TOC) Analyzer detection technology, which offers true Carbon measurement without the risk of interference from compounds, which could affect accuracy.

TOC and conductivity are metrics that drug manufacturers must monitor to comply with complex regulations. The importance of these technologies is in the way they enable water users to go beyond compliance and achieve optimization and control. TOC and conductivity data help facilitate better understanding and control of process and product quality. TOC data can be used in a variety of applications to increase efficiency and optimize resource use through automation.

In the life sciences industry, where ultra-pure water (UPW) is critical to ensuring the safety of drugs and medical devices, Sievers M500 saves time during real-time pharmaceutical water-release testing, reducing water analysis costs and ensuring compliance with pharmacopoeia standards.

Many different compounds can be measured with TOC analysis for validation and cleaning verification, including APIs, detergents, degradants and excipients. Water soluble compounds can be analyzed using TOC analysis with little to no method variation. TOC Sievers analyzers, consumables and SUEZ's expertise respond to diverse development methods to ensure a smooth operation.

Benefits of SUEZ Sievers

The M500 Sievers Series is the third generation of online TOC analyzers, designed for accuracy, efficiency and data

integrity. Building on the proven results of the 500 RL series, the M500 series enhances SUEZ's performance as an industry pioneer and adds a range of cutting-edge features, such as automated iOS 4-port samplers to improve efficiency as such, M500 is revolutionizing online detections of organics, new performance, design and data management features. A 50 percent reduction in analysis time facilitates the use of real-time data and enables early detection and process control. The 10-inch touch screen allows for quicker and easier setup and operation. Furthermore, its systematized and personalized protocols improve productivity.

During sampling, consistent swabbing techniques and null contamination are a must for cleaning validation. Thus, choosing the right, high-quality consumables for this application is critical for accurate TOC and conductivity measurements. SUEZ provides custom reference standards for unique applications, in addition to providing specialty vials and a wide range of accredited and certified reference materials.

Sievers instruments also improve processes to determine the suitability of verification systems that assess the relative recovery of two compounds: sucrose and benzoquinone. The instruments establish and validate adequate flow rates for a defensible and consistent methodology. This must be performed with a certain frequency, which must be determined internally based on the risk of failure.

Efficacy and Efficiency

Among the most outstanding innovations of SUEZ's tools are their digital upgrades, including Wi-Fi, improved data transfer and management options and security features to preserve data integrity. Moreover, Sievers M500 powers industry-leading TOC data management tools to ensure data security. It is compliance with 21 CFR Part 11 and FDA guidelines regarding data integrity.

Sievers M500 TOC has a range of 0.03ppb to 2.5ppm, a detection limit of 0.03ppb and a limit of quantification of 0.1ppb. Its measurements follow USP, EP, JP, IP, ChP and KP pharmacopoeias and all other harmonized standards. Instruments offer a 50 percent reduction in analysis time, as well as simultaneous measurement of TOC and conductivity.

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