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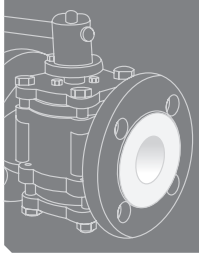

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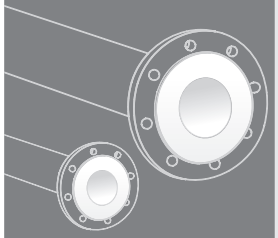

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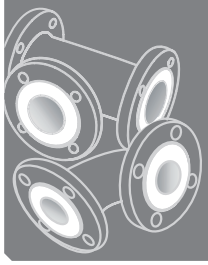

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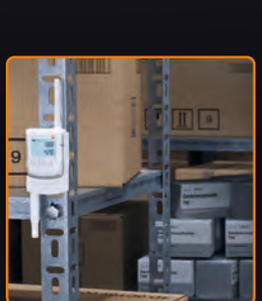



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Union Minister Dr Jitendra Singh dedicates to the nation, India's first national repository for life science data- 'Indian Biological Data Centre' (IBDC) at Faridabad, Haryana

Faridabad, India: Dr Jitendra Singh said, as per the BIOTECH-PRIDE guidelines of the Government of India, IBDC is mandated to archive all life science data generated from publicly funded research in India. Supported by the Department of Biotechnology (DBT), it has been established at Regional Centre of Biotechnology (RCB), Faridabad with a data 'Disaster Recovery' site at National Informatics Centre (NIC), Bhubaneshwar.

It has a data storage capacity of about 4 petabytes and houses the 'Brahm' High Performance Computing (HPC) facility. The computational infrastructure at IBDC is also made available for researchers interested in performing computational-intensive analysis. Users can contact the data centre by submitting their requests at support@ibdc.rcb.res.in

Dr Jitendra Singh informed that IBDC has started nucleotide data submission services via two data portals viz. the 'Indian Nucleotide Data Archive (INDA)' and 'Indian Nucleotide Data Archive - Controlled Access (INDA-CA)' and has accumulated over 200 billion bases from 2,08,055 submissions from more than 50 research labs across India.

Fundamentally, IBDC is committed to the spirit of data sharing as per FAIR (Findable, Accessible, Interoperable, and Reusable) principles. IBDC is being developed in a modular fashion wherein different sections would typically deal with type/s of life science data.

The computational infrastructure at IBDC is also made available for researchers interested in performing computationally intensive analysis. Users can contact the data centre by submitting their requests at support@ibdc.rcb.res.in.

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Bharat Biotech's iNCOVACC receives primary series and heterologous booster approval

Hyderabad, India: Bharat Biotech's iNCOVACC has received approval from the Central Drugs Standard Control Organisation (CDSCO) under restricted use in emergency situation for people aged 18 years and above, in India, for heterologous booster doses, said the company in a statement released to the public.

According to the statement, iNCOVACC is a recombinant replication-deficient adenovirus-vectored vaccine with a pre-fusion stabilised SARS-CoV-2 spike protein. This vaccine candidate was evaluated in phases I, II and III clinical trials with successful results. iNCOVACC has been specifically formulated to allow intra-nasal delivery through nasal drops. The nasal delivery system has been designed and developed to be cost-effective in Low- and Middle-Income Countries (LMICs).

Further, iNCOVACC was developed in partnership with the Washington University, St Louis, which had designed and developed the recombinant adenoviral vectored construct and evaluated in pre-clinical studies for efficacy. Product development related to pre-clinical safety evaluation, large-scale manufacturing scale up, formulation and delivery device development, including human clinical trials were conducted by Bharat Biotech.

Biocon Biologics acquires Viatris's global biosimilars verticals

Bengaluru, India: Biocon Biologics has completed its acquisition of the global biosimilars business of its partner Viatris. All applicable approvals from key global regulators including the US Federal Trade Commission (US FTC), the Competition Commission of India (CCI), the Reserve Bank of India (RBI), and its investors have been granted to companies involved in the said matter.

Biocon Biologics will recognise the combined revenue and associated profits from the acquired products, a step-up from the existing profit share arrangement, effectively, from the date of closing. The acquisition provides Biocon Biologics with direct commercial capabilities and supporting infrastructure in the advanced markets and several emerging markets, bringing it closer to patients, customers, and payer, said the statement.

The statement also said, Biocon Biologics has full ownership of its collaboration assets, bTrastuzumab, bPegfilgrastim, bBevacizumab, bGlargine, bAspart, bPertuzumab and bGlargine 300U, as well as Viatris's rights for the in-licensed immunology products of bAdalimumab and bEtanercept. Biocon

Biologics has also acquired Viatris's rights for bAflibercept, which is used to treat several ophthalmology conditions.

Gland Pharma to acquire 100 per cent of Cenexi Group via a Put Option Agreement

Hyderabad, India: Gland Pharma to acquire 100 per cent of Cenexi Group via a Put Option Agreement for an equity value not exceeding 120 million euros.

As per the statement detailing the transaction, Cenexi, along with its subsidiaries, is engaged primarily in the business of Contract Development and Manufacturing Organisation (CDMO) of pharma products with expertise in sterile liquid and lyophilised fill-finished drug, including capabilities on oncology and complex products. It has presence across four manufacturing sites in Europe which include three sites in France and one site in Belgium.

Gland Pharma has a strategic focus on expanding its CDMO offerings in the European market and build a manufacturing presence in the market. The acquisition provides the company access to leading know-how and development capabilities in sterile forms, including for ophthalmic gel, needleless injectors, and hormones. Gland Pharma's ability to support future investments in expanding manufacturing footprint will help build Cenexi as a major CDMO player in the European market, explained the statement.

Aurobindo Pharma's unit and Evive Biotech enter into a licensing pact to commercialise CIN treatment product in US

Hyderabad, India: Aurobindo Pharma said its unit has entered a licensing pact with Evive Biotech to commercialise Ryzneuta in the US market.

The product, a novel dimeric G-CSF long-acting fusion protein without pegylation, is currently under late-stage review by the US Food and Drug Administration (FDA) for Chemotherapy-Induced Neutropenia (CIN). In addition to the US health regulator, Evive's Marketing Authorisation Application (MAA), and New Drug Application (NDA) for Ryzneuta are currently under review by the European and Chinese regulators.

The licensing pact has been inked between Evive and Acrotech Biopharma (Acrotech), a New Jersey-based and wholly owned subsidiary of Aurobindo Pharma USA Inc, Aurobindo Pharma said in a statement. As part of the agreement, Evive will be responsible for the ongoing development, manufacturing, registration, and supply of Ryzneuta, while Acrotech will use its sales and commercialisation capabilities to market and distribute the product in the US, it added.

"Ryzneuta provides Acrotech the opportunity to expand its offerings to oncology patients and is aligned with our vision of commercialising scientifically advanced products. Additionally, expanding into CIN creates future growth opportunities for us," Ashish Anvekar, President, Acrotech Biopharma, said.

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Biovac signs Transfer of Technology deal with International Vaccine Institute to globally develop Oral Cholera Vaccine

Cape Town, South Africa: Biovac Institute has signed a licensing and technology transfer deal with the International Vaccine Institute (IVI) to develop and make oral cholera vaccine for African and global markets, the companies said.

The partnership with non-profit IVI, headquartered in South Korea, aims to boost output, and reduce vaccine shortages amid a spate of global outbreaks that spurred the World Health Organization (WHO) to temporarily change its dosage regime.

"This initiative will be the beginning of end-to-end vaccine manufacture at Biovac, while at the same time addressing an ongoing and increasing cholera disease burden globally," Morena Makhoana, Chief Executive of the company, said in a statement.

Technology transfer would start in January next year, with the first clinical trial batches expected in 2024, ahead of licensing by domestic regulators and WHO pre-qualification certification said the Chief Executive.

"We will then be well placed to supply UN agencies, such as WHO and UNICEF/GAVI, as many African countries and other least developed countries source their vaccines through this mechanism" added the Chief Executive.

Lupin signs agreement to acquire two inhalation brands from Sunovion

Mumbai, India: Lupin Pharma has signed an agreement to acquire all rights to two inhalation medicines, Brovana (arformoterol tartrate) Inhalation Solution and Xopenex HFA (levalbuterol tartrate) Inhalation Aerosol, from Sunovion Pharma for a price of 75 million USD.

The company statement states the acquisition of these two brands expands Lupin's portfolio of inhalation products in the US and strengthens the company's presence in the respiratory therapy area while continuing to provide patients access to these important medicines.

As per the statement, Brovana is indicated for long-term maintenance treatment of bronchoconstriction in patients with Chronic Obstructive Pulmonary Disease (COPD), including chronic bronchitis and emphysema, Xopenex HFA is a short-acting beta2-adrenergic agonist (SABA) indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children four years of age or older with reversible obstructive airway disease.

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Zeon Lifesciences upgrades its Paonta sahib plant with AI and Industry 2.0 automation

Himachal Pradesh, India: Zeon Lifesciences has upgraded its Paonta sahib plant with Artificial Intelligence (AI) and Industry 2.0 Automation for business growth and innovation with the goal of focussing on new innovations and research advancements in India's Nutra industry.

Company's media release states, new developments that were undertaken as a part of the upgrades at the existing plant towards plant advancement includes the implementation of ZEMANEX's new operating model (Zeon Manufacturing Excellence- the new way of working), the formation of a new independent vertical: manufacturing compliance, the implementation of the new First Line Leader (FLL) concept for better accountability and responsibility et cetera.

Advancements in terms of capacity improvement, a focussed perspective on zero faults, zero waste, zero accidents, cost optimisation, diverse clientele, and a greater ability to handle diverse clients and diverse demands of all dose forms, the statement added.

AstraZeneca to acquire Neogene Therapeutics

Cambridge, England: An agreement to acquire Neogene Therapeutics Inc. (Neogene), a global clinical-stage biotechnology company pioneering the discovery, development, and manufacturing of next-generation T-cell receptor therapies (TCR-Ts) that offer a novel cell therapy approach for targeting cancer was announced by AstraZeneca.

With a goal of bringing cell therapies to patients with solid tumours, Neogene's expertise in TCR-T discovery, development and manufacturing will strengthen AstraZeneca's ambition to transform outcomes for patients.

TCR-Ts are emerging as a promising therapeutic modality in cancer treatment. Most current cell therapy approaches in oncology focus on modifying the immune system's T cells to recognise proteins expressed on the surface of cancer cells. In contrast, TCR-Ts can recognise intracellular targets, including cancer-specific mutations, thereby potentially unlocking targets previously inaccessible using cell therapies.

AI tailors artificial DNA for future drug development

Gothenburg, Sweden: With the help of an AI, researchers at Chalmers University of Technology have succeeded in designing synthetic DNA that controls the cells' protein production. This technological breakthrough can contribute to the development and production of vaccines, drugs for severe diseases, as well as alternative food proteins much faster and at comparably lower costs.

How human genes are expressed is a process that is fundamental to the functionality of cells in all living organisms. Simply put, the genetic code in DNA is transcribed to the molecule messenger RNA (mRNA), which tells the cell's factory which protein to produce and in which quantities.

Most of today's new drugs are protein-based, but the techniques for producing them are both expensive and slow, because it is difficult to control how the DNA is expressed. Last year, a research group at Chalmers, led by Aleksej Zelezniak, Associate Professor of Systems Biology, took an important step in understanding and controlling how much of a protein is made from a certain DNA sequence.

Glaxo Smith Kline announces positive Phase II A study results for a new first-in-class candidate medicine for patients with tuberculosis

London, England: Glaxo Smith Kline announced positive results from a Phase IIa study demonstrating that GSK3036656, a first-in-class investigational antitubercular agent, was well tolerated among the trial participants and showed early bactericidal activity with a low, once-daily (OD) oral dose after 14 days of treatment in participants with drug-susceptible pulmonary tuberculosis. These results demonstrate the potential for the novel medicine candidate to be a component of simpler treatment regimens in the future which could help address the TB epidemic.

Anti-mycobacterial activity was demonstrated both in terms of reducing the number of viable TB cells which are able to multiply and an increase in the time to detect bacterial growth in culture. In addition, PET CT imaging of the lungs showed a reduction in TB disease over 14 days in all participants taking GSK3036656 30mg, the report stated.

"Existing treatments for TB can be complicated, of long duration and have serious side effects which significantly impact the lives of patients with TB around the world. Today's encouraging data provide a good foundation from which to investigate GSK3036656 in different combinations in Phase IIb/c studies, with the aim of contributing to shorter, simpler, and better tolerated treatment regimens for patients with TB" said David Barros-Aguirre, Head of Global Health Medicines R&D, GSK.

US Food and Drug Administration (US FDA) approves first gene therapy to treat adults with Haemophilia B

Maryland, United States: US FDA approves Hemgenix (etranacogene dezaparvovec), an adeno-associated virus vector-based gene therapy for the treatment of adults with Haemophilia B (congenital Factor IX deficiency) who currently use Factor IX prophylaxis therapy, or have current or historical life-threatening haemorrhage, or have repeated, serious spontaneous bleeding episodes.

Dr. Peter Marks, Director of the US FDA's Centre for Biologics Evaluation and Research said "Gene therapy for haemophilia has been on the horizon for more than two decades. Despite advancements in the treatment of haemophilia, the prevention and treatment of bleeding episodes can adversely impact individuals' quality of life." they added,

"Today's approval provides a new treatment option for patients with Haemophilia B and represents important progress in the development of innovative therapies for those experiencing a high burden of disease associated with this form of haemophilia."

Granules enters pharma packaging business in US, to invest 12.5 million USD in new unit at Prince William County, Virginia.

Hyderabad, India: Granules Pharma has said in a statement that the company has forayed into pharmaceutical packaging operations in United States and will be investing a sum of 12.5 million USD in a new facility at Prince William County, Virginia.

A 79,000 sq. ft. facility will be leased at Prince William County where it will setup packaging lines and clean rooms to pack and ship pharmaceuticals. The facility will be a part of company's consumer health division.

Mylab launches indigenous kit and automated devices for TB and multi-drug resistance

Pune, India: Mylab has received CDSCO, TB Expert Committee and ICMR approval for first Made in India TB Detection Kit to detect tuberculosis, which also simultaneously detects multiple drug resistance to rifampicin and isoniazid in single test. The kit is named PathoDetect MTB RIF and INH drug resistance kit. This PathoDetect kit combined with Mylab Compact device platform will fill the current gaps in Tuberculosis testing, a disease which caused more deaths every year than the Covid-19 second wave.

Hasmukh Rawal, MD, Mylab said, "We are addressing several problems simultaneously here. First being able to speed up testing by automated systems that can do multiple tests at one time. Secondly, there is scarce trained manpower for RT-PCR testing, which India can now overcome with fully automated system which does not need highly technical person to handle samples and reagents."

Alembic Pharmaceuticals receives USFDA nod for Diclofenac Sodium Topical Solution USP 2%

Vadodara, Gujarat: Alembic Pharmaceuticals Limited announced that it has received final approval from the US Food & Drug Administration (US FDA) for its Abbreviated New Drug Application (ANDA), diclofenac sodium topical solution USP, 2% w/w. The ANDA was filed by Aleor Dermaceuticals Limited which was amalgamated with Alembic.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD),

Diclofenac sodium topical solution is indicated for the treatment of the pain of osteoarthritis of the knee(s). Refer to our label for full indication. Aleor had previously

received tentative approval for this ANDA. Alembic Pharmaceuticals Limited as of yet have received a cumulative total of 177 ANDA approvals (154 final approvals and 23 tentative approvals) from US FDA.

JB Pharma gets US FDA nod for Venlafaxine ER tablets

Mumbai, India: JB Pharma, has announced that it has received final approval from US FDA for its Abbreviated New Drug Application (ANDA), venlafaxine extended-release tablets 37.5 mg, 75 mg, 150 mg, and 225 mg.

This product is based on OROS (osmotic controlled release oral delivery system) technology, an advanced and precision-controlled release mechanism – an area where JB has seen success with 3 products already in the US market. JB Pharma now has 17 US ANDA approvals.

The generic product approval is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), venlafaxine hydrochloride extended-release tablets, 37.5 mg, 75 mg, 150 mg, and 225 mg, of Osmotica Pharmaceutical US LLC. A selective serotonin and norepinephrine reuptake inhibitor (SNRI), venlafaxine extended-release tablets are indicated for major depressive disorder (MDD) and social anxiety disorder (SAD).

Nikhil Chopra, CEO and wholetime director, JB Pharma said, "Venlafaxine extended release tablets will be our fourth offering in the US market based on advanced OROS (osmotic controlled release oral delivery system) technology, which demonstrates JB Pharma's ability to leverage and deliver quality products using its OROS platform and deliver high quality medicines to patients. We remain committed to expand our brand portfolio in structured and strategic way."

VAV's Lipid Solutions for Advanced Vaccines and Formulations

Mumbai, India: VAV's high-quality lipids demonstrate significant potential towards enabling pharmaceutical companies to develop multiple projects in drugs and biologics delivery. These included applications of lipids in developing thermostable vaccines and formulations, cancer therapy based on liposomes, and treatment of chronic autoimmune and neuromuscular diseases like myasthenia gravis and multiple sclerosis.

There has been a specific interest in new upcoming technologies based on lipids, especially in the development of antibodies, RNA, oligonucleotides, and several advanced medical products. There was also interest in VAV's lipids for developing animal vaccines and aquaculture. The applications of lipids in reformulating generic drugs to make them more efficient also received significant attention from global generic pharmaceutical companies.

Arun Kedia, Managing Director, VAV Lipids, said, "This highlights the disruptive potential of lipid nanotechnology in healthcare. Our technology helps address untreatable disease segments and will indeed offer hope to patients suffering from these diseases. We are looking to partner with various major healthcare companies in our quest to make healthcare delivery better."

US FDA, India Office opens 'Centre of Excellence in Regulatory Sciences' at JSS College of Pharmacy, Mysuru

From Left: Dr. M.P. Venkatesh, Associate Professor, JSSCPM; Dr. T.M. Pramod Kumar, Principal, JSSCPM; Dr, Sudheendra Kulkarni, US-FDA INO; Mr. Gregory Smith, US-FDA INO; Dr. Sarah McMullen, Country Director, US-FDA INO; Dr. C.G. Betsurmath, Executive Director, JSS Mahavidyapeetha; Dr. Surinder Singh, Vice Chancellor, JSS AHER; Mr. Dhruv Shah, US-FDA INO; Dr. Prashanth Vishwanath, Dean (Research), JSS AHER and Dr. Balamuralidhara V, HoD, Dept. of Pharmaceutics, JSSCPM

Mysuru, India: US FDA, India Office, which opened a 'Centre of Excellence in Regulatory Sciences' at JSS College of Pharmacy, Mysuru is envisaged to spur potential partnerships which could enable knowledge management and create a pool of required pharmacy professionals. This is the first of its kind Centre of Excellence in Regulatory Sciences. Dr. Sarah McMullen, Country Director, US FDA India Office (INO) inaugurated the 'Centre of Excellence in Regulatory Sciences' at the JSS College of Pharmacy, Mysuru.

The key objective of the Centre is to make available a pool of competent professionals in regulatory affairs with fundamental knowledge on various good regulatory practices. The intent is also to provide a focal point for knowledge management, with the ability to capture new knowledge and practices from the healthcare sector. ■

Quality Assurance & Compliance Management in Pharmaceutical Industry

Each year, the pharmaceutical industry releases several new drug products into the market, either as novel therapeutics for unmet medical needs or as modified generics/biosimilars. The released product must be safe enough without severe life threatening fatal adverse events and must work for intended therapeutic indication. Regulatory agencies frequently publish new guidelines, for any sudden, unanticipated safety related incidents that may manifest in patients. Both Industry and agencies investigate to understand why these unanticipated events occurred. This includes going back to the laboratory methods, procedures, clinical trial design and identifying gaps and/or inadequate procedures that may have resulted in unforeseen unsafe incidents.

In some instances, companies may have poor and inadequate Quality Compliance (QC) management processes resulting in the release of substandard products. In other instances, quality of available compliance systems may not be adequate enough to predict or anticipate rare, unsafe Adverse Drug reactions (ADR) those may occur in more than 2 million patients, each year, by drugs already on the market. It is estimated that 3 – 7% of hospitalizations are due to ADR and each year more than 100,000 patients die of ADR, in the United States alone. In such cases companies and agencies work together and introduce additional new QC systems with new regulatory guidelines to prevent such unsafe events from happening again in the future. A good example in this regard is to proactive adherence to guidelines and recommendations by agencies, at preclinical and phase 1 clinical trials stages, ensures prevention of drug-drug interactions leading to fatal hepatotoxic and cardiotoxic events.

Recently, WHO linked deaths of nearly 70 children died with consumption of cough syrup manufactured and exported from India. The presence of lethal concentrations of diethylene glycol and

ethylene glycol were found in this cough syrup which led to kidney failure in these children. The poor-quality management and subsequent release of such products into the market can prove to be deadly for the consumers.

Flupitrine, an opioid analgesic was approved for chronic pain management and later withdrawn from the market in European Union by EMA due to its liver toxicity and failure in humans. In 2013, EMA restricted the use of Flupitrine for acute pain but later in 2018 asked the manufacturer to remove the drug from the market due to poor compliance of clinical practice for the recommended restricted use.

Thus, pharmaceutical Research and Development (R&D) as well as manufacturing practices are strictly under regulatory surveillance and must comply with regulatory guidance. Regulatory agencies, such as US- FDA (United States-Food & Drug Administration, EU-EMA (European Union-European Medicines Agency), IN-DCGI (India-Drug Control General Authority) issue guidance documents for many drug development and manufacturing activities which must be followed by all companies. In addition, all companies are mandated to follow GXP regulations such as Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), and Good Clinical Practice (GCP) issued by regulatory authorities. Compliance to these regulatory rules during R&D and manufacturing practices is expected to release high quality pharmaceutical products into the market.

Quality is an inherent required attribute of any product released into the market. Thus, Quality is simply defined as: "the standard of something as measured against other things of a similar kind; the degree of excellence of something."

Quality Compliance, however, must abide to rules imposed by regulatory agencies and is defined as: "the action or fact of complying with a wish or command."

In other words, if a regulatory agency of any given region sets some rules, companies conducting R&D and/ or manufacturing must abide those rules when developing and bringing a product(s) to market. In drug discovery and development (including health products, medical devices, diagnostic equipment) the companies those deliver products or services, must ensure high quality R&D, but also need to comply with QC regulations and successfully pass during the regulatory audits. Poor QC of products has direct impact on health of patients leading to mis-diagnosis/-prognosis, lack of desired effect in patients, and

Regulatory Agencies Involved in Setting QA & QC Standards	
United States-Food & Drug Administration	US- FDA
European Union-European Medicines Agency	EU-EMA
India-Drug Control General Authority	IN-DCGI

sometimes fatal adverse events.

Regulatory agencies, therefore, have the authority to

(a) not approve the product

(b) ask the company to withdraw or recall the product and

(c) shut down the companies who do not abide by rules.

Regulations of QC: Many regulations pertaining to GXP (GLP, GMP, GCP) are issued by agencies. Companies wishing to seek regulatory approvals for their products must strictly adhere to these GXP practices. In addition, agencies also release guidance documents on

"Harmonized" practices (e.g., International Conference on Harmonization - ICH) across industry in various countries/ regions, to ensure clinically meaningful and reproducible results are obtained. Regulatory agencies perform frequent audits on companies who submit their products for approvals and reject those products that do not comply with regulatory standards. All companies, thus, have a "Quality Assurance (QA)" team and design processes to ensure highest QC. The structures of the teams may vary from company to company, but these teams will ensure high QC measures to regulatory standards.

The GXP Regulations	
GMP	Good Manufacturing Practices
GLP	Good Laboratory Practices
GCP	Good Clinical Practices

Quality Assurance Team and its role in managing Quality Compliance:

Quality Assurance is defined as "the maintenance of a desired level of quality in a service or product, especially by means of attention to every stage of the process of delivery or production." A QA team, typically, directly reports to the head of the organization, along with respective scientific heads and is responsible for

▪ Standard Operating Procedures (SOPs):

All equipment, experimental procedures, protocols, study reports, documentation in laboratory notebooks/e-lab notebooks, all raw data, computers used in all the data generation and storage – SOPs must be prepared by the appropriate scientist(s) with the help of QA team.

These SOPs must be signed by the scientist and department head with a commencing and expiry dates of compliance activity. Scientist(s) responsible for SOP must be trained to ensure strict adherence to the activities listed in the SOP. QA team monitors/audits portions of the study for compliance. All original SOPs are the property of QA team and filed in their archival area. The respective QA auditor alerts the appropriate scientist, in advance, when a SOP is due to expire and reissues the SOP with any latest modifications required.

▪ **Equipment and Method Validation:**

Frequent validation procedures for all equipment used in the "regulatory compliant" studies must be in place. Validations require SOP defined criteria with a valid reference recommended by regulatory agency. These include computers, printers and data storage systems used in the data, report and regulatory submission document generation and retrieval. Any non-validated equipment, if used in a GLP study the entire study may be considered non-compliant and need to be repeated. Quality Assurance teams must assure scientists adhere to all the required validations.

All study protocols and reports must follow regulatory protocols. These include listing the STUDY DIRECTOR (SD) and STUDY INVESTIGOTOR (SI) names for each sub-part of the study. For example, in a regulatory toxicology study, a SD is responsible for overall Toxicology study design and conduct, including the sub-parts of the study by other experts - histopathological analysis by pathologist; bioanalysis by bioanalytical scientist; toxicokinetic analysis by a pharmacokineticist, and so on. Any deviations to the protocol must be documented with a justification for the deviation and obtain permission by the SD before implementing the deviation. In addition, if any new research investigations are to be conducted, which are not part of the GLP protocol (e.g., metabolite and biomarker analyses) also require SD approval and must be documented as to their non-GLP status. The protocol must list the dates of study initiation including dates of the sub-parts for the study.

Maintenance of laboratory and e-notebooks, raw data:

Quality Assurance group issues all laboratory notebooks (LN) to the scientists. A LN issued for one study may not be used for another study. During the issuance of LN, scientists must sign a document (along with the QA representative) with day/date the LN issued along with details of the study. Study-specific raw data, such as calculations etc. must be documented and archived co-signed by the scientist and team head. In addition, if any errors that need to be changed in the LN must be reviewed/approved by the immediate supervisor and both must initial/sign as defined in the SOP. The quality assurance group is responsible for the archival of all wet and dry samples, protocols, reports, audit trails – in a locked and fireproof storage area with a dedicated person in charge.

Coordinating audits with regulatory agencies and external clients:

The quality assurance team is the primary contact for regulatory audits, internal mock audits, and external client audits. They provide all the necessary documents including SOPs, and training records of

employees, GLP study compliance list and any other documents as required.

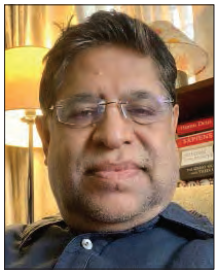
Conclusion

Quality compliance is a regulatory mandate. However, QA team structure of any company is not mandated by the regulatory agencies provided companies comply with the regulatory mandates. Documentation of all the research methods and data is absolutely essential for any submission. Many scientists conducting basic science research may argue that they are conducting research out of compliance jurisdiction and need not follow the regulations. Today, many companies require for "FULL DISCLOSURE" submitting both non-GXP and GXP data in their submissions. In such case, any data generated by non-GXP methods are also reviewed by agencies and any irregularities/ discrepancies in non-GXP and GXP data may be questioned by agencies. Failure to address those queries by regulatory agencies may create more regulatory hurdles including delays in approval or non-approval.

Approximately 40–70% or more of the academic data is non-reproducible in a regulatory compliant protocol when pharma companies repeat the studies by pharma scientists. Thus, it has become a normal process when an academic research organization tries to out-license a product (especially when the data generated thru non-regulatory compliant procedures) to an industrial partner, the in-licensing company may insist on repeating the study in their own hands to the reproducibility of the study, before committing to in-licensing. Thus, it is essential to maintain high level Quality Compliance of all research activities, in any organization (academic or industry), whether or not the research and manufacturing activities conducted under GXP or non-GXP conditions. Adherence to high quality R&D is in the best interest of any organization to prevent regulatory hick-ups and for successful registration of their products with minimum timelines and minimum budgets. ■

Authors

Dr Subrahmanyam Vangala
CEO
Reagene Biosciences Pvt Ltd

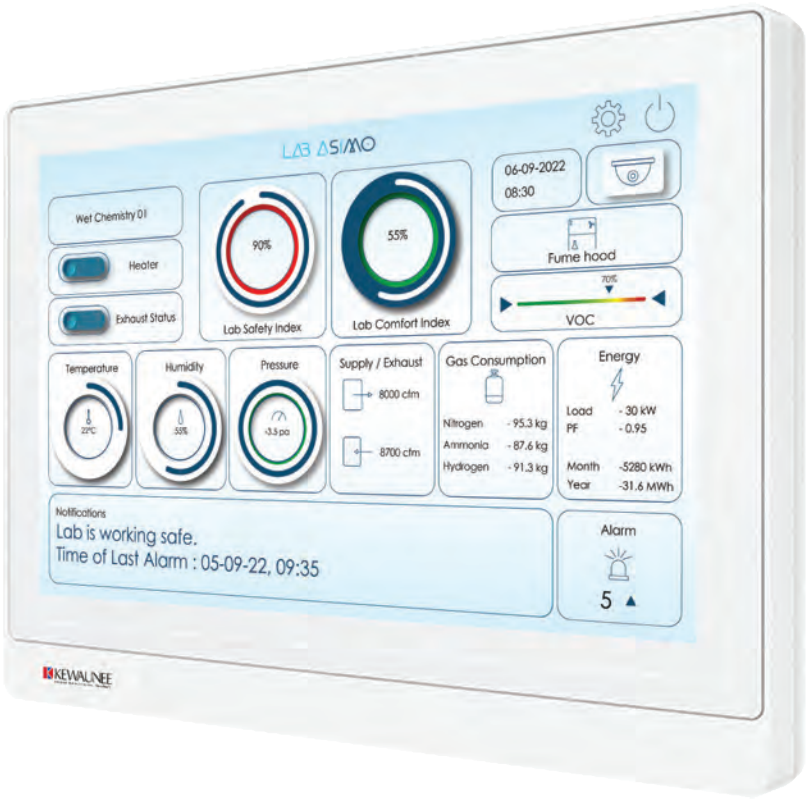


Dr Uday Saxena
Co-founder & Chief Ideator
Reagene Biosciences Pvt Ltd

Dr Prema Kolachana
Managing Director
Reagene Biosciences Pvt Ltd

Innovations in Lab & Analytical Technologies

New ideas, processes, and advances begin with innovation. Digitization is revolutionizing the world we live in, and laboratories are no different.



Why Lab Digitization?

Scientists and Analysts need safe and controlled Lab space free of contaminants with high-throughput technologies that allow laboratories to streamline Research & Development (R&D) and drive innovation in fundamental research, improving the speed, cost control, and efficiency of tests so that they can do what they are good at.

Digitization and automation categorically can also assure better quality and compliance by reducing manual errors and variability. They enable faster and more effective problem resolution and a risk-based approach to optimizing testing volume, tools, and methods.

The latest technologies and digital solutions can make quality control faster, more agile, more reliable, more compliant, and more efficient.

Continuous Monitoring of lab equipment is crucial to prevent malfunction, reduce downtime, improve efficiency, and ensure product safety. The insights from equipment monitoring can help to optimize equipment usage so that the assets run at peak performance, avoiding excessive

energy consumption caused by equipment working overtime and also help to improve energy efficiency in any lab through schedule management.

Also, Let's understand

How can data analytics help fuel innovation and could be a game-changer?

Data is the fuel for unlocking value through digital technology. More data and accurate data are vital for a better solution. However, as the amount of digital data grows it's a burden to manage data and provide accurate results. Regardless of the type of laboratory, discovery, research, or industrial, the accuracy of results and insight are critical to creating new products or driving forward scientific discoveries.

Furthermore, quality assurance and quality control are of utmost importance at all stages of a pharmaceutical product's development to ensure the safety & compliance of products before these reach the market and finally to consumers

It is a fact that digitalization has the potential to enhance pharmaceutical quality assurance and quality control significantly. For example, a typical pharma lab does not have the advanced analytical capabilities needed to get the maximum value from its data sources. As a result, the labs collect a lot of useful data but fail to generate insights that could prevent problems, improve test methods, or optimize testing volumes. However, with digitalization IoT Powered Integrated Laboratory Monitoring Solutions can communicate with each other and share data, giving insight and thus allowing them to automatically identify potential quality control issues. That is why the application of new technology is inevitable for productivity, accessibility, security, and sustainability.

The emerging technologies that characterize Industry 4.0—from

Continuous monitoring for a wide range of parameters like via Lab Asimo

- Monitoring the Air Quality of the Laboratory
- Laboratory HVAC Monitoring
- Comfort for Laboratory users
- Monitoring fume hood performance
- Monitoring of essential common services like Gases
- Energy monitoring and optimization

connectivity to advanced analytics, robotics, and automation—have the potential to revolutionize every element of

the pharma-manufacturing labs. Enabling the R&D industry to achieve sustainability, harvest the fast-growing wealth of data, and turn it into actionable insights for a better solution and enhanced financial results.

Complete solution for Monitoring and Reporting in Regulated and Critical Environments

It's important to maintain acceptable levels in the internal atmosphere of a lab, such as temperature, humidity, volatile organic compounds (VOCs) and CO2/O2 levels along with Monitoring of essential common services like Gases, Energy monitoring and optimization.

IoT Powered Integrated Laboratory Monitoring Solution

In the Laboratory industry, technologies such as Kewaunee's Lab Asimo have created a platform that solves all the 4.0 initiation challenges. Lab Asimo is the way to realize an organization's goal for of a complete solution towards monitoring and reporting in regulated and critical environments.

Such integrated technologies also offer a unique Lab Health Index, a revolutionary and compressive safety report on fume hood performance and utilization.

Lab Health Index (LHI)

LSHI will assist in safeguarding the laboratory monitoring integrity with regard to identifying all of the procedures and practices that are prone to error, inefficiencies, and safety hazards.

Analytical reports

Lab Asimo enables the transformation of raw data into valuable insights for non–intrusive monitoring and preventive maintenance. With quality control systems, laboratories can run more efficiently to guarantee accurate production and reproducible results. ■

Author

Sathya Murthy
Managing Director
Kewaunee International Group

The Smart Choice for Laboratory Equipment

Role of Microbiological Laboratory Equipment in Quality Control of Pharmaceutical Industry

QC and QA in Pharmaceutical Industry

Quality Control and Quality Assurance is the process of inspecting and approving products to ensure they meet the required customer and regulatory standards. Quality control (QC) is an important part of quality management in a pharmaceutical setting whereas Quality assurance (QA) is the process of making sure quality requirements have been fulfilled.

Without QC & QA functions of quality management, a pharmaceutical organization would struggle to achieve consistency in its output. These two quality management systems are highly important and contribute to productivity and the overall success of an organization's products.

Quality Control (QC) in Pharmaceutical Industry:

Quality control goes beyond just checking the finished product. Pharma companies must consider every aspect of quality control, from verifying the quality of the raw materials going into the process, the production steps that may change the makeup of those materials and ensuring that standard operating procedures have been followed in every step until the final product ships out.

The main objective of quality control in the Pharmaceutical Industry is to test the drugs in their various stages of production, verifying that they can proceed to the next stage and release the manufacturing process following the regulations and specifications required for consumption.

The complete control of the quality of the medication that is being produced needs to be tested in several work areas. The main areas of research and analysis are:

- Physical-Chemical Laboratory
- Microbiological Laboratory
- Packaging Material Laboratory
- Process Control Laboratory

The quality control (QC) microbiology laboratory plays an essential role in pharmaceutical manufacturing and product release.

The microbiology lab is the place where all microbiological tests and analyses occur, it has special preparations in design and precautions as the hazard material here is Microorganisms-which might be infectious- which is different from the chemical and physical lab as these pathogens can multiply or transfer out of the lab if precaution is not followed.

Different equipment and instruments are used in a microbiology lab, some of the basic devices needed in the Microbiology laboratory are listed here.

Apart from drugs and bio products development, microbiology contributes to the quality control of a pharmaceutical laboratory. Prevention of microbial contamination of drugs, injectables, eye drops, nasal solutions, and inhalation products is undertaken following pharmacopeial guidelines.

Microbiological Test Methods Include the following testing methods:

- The Growth Promotion test
- Sterility Testing.
- Microbial Limits Test
- Bioburden Testing
- Water Analysis
- Bacterial Endotoxin (LAL Testing)

Different equipment and instruments are used in Microbiological testing methods, some of the basic instruments needed are listed here, which play an important role in maintaining the quality of the final product.

Laminar flow cabinets are an enclosed bench designed to prevent contamination of microbiological samples. Where the air is drawn through a HEPA filter and blown in a very smooth, laminar flow toward the user.

Biosafety Cabinets (BSCs) are enclosed workspaces with a ventilated hood that is designed to contain pathogenic microorganisms during

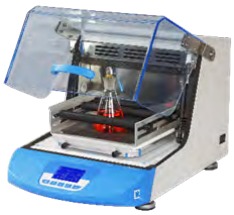
microbiological processes, protecting the User, Product, and Environment.

Freezers are used in storing media under low temperatures to prevent microorganism growth and to avoid dehydration of the media.

Incubators are general laboratory devices used to maintain the growth of Microorganisms through

controlling temperature, humidity, or other factors which is essential for the growth of certain types of Microorganisms. BOD Incubators, C02 incubators, and Shaking incubators are widely used.

Water baths are used to maintain the



samples at a constant temperature over a long period.

Orbital shakers are ideal for a variety of general-purpose shaking applications in cell culture, bacterial growth, suspension, staining, and washing procedures.

Ovens are used to sterilize biohazard waste, dissecting instruments, or media/

reagents for aseptic assays. Drying ovens, Vacuum ovens are widely used.

Drug quality and safety is the most important aspect of microbiological testing of pharmaceutical products. The presence of any pathogenic bacteria, yeasts, moulds, or bacterial toxins produced by microorganisms is strictly regulated to ensure the prevention of any risk.

Conclusion

Quality control is an essential operation of the pharmaceutical industry. Drugs must be marketed as safe and therapeutically active formulations whose performance is consistent and predictable. New and better medicinal agents are being produced at an accelerated rate. At the same time, more exacting and sophisticated analytical methods are being developed for their evaluation.

Microbiological laboratory equipment plays a great role in producing the product with maintained quality and ensures the safety of the product. ■

Author

Arun Mathrubootham
Business Development Manager
Inkarp Instruments Private Limited

Automated Climate Monitoring

Both pharmaceutical and medical technology products directly influence the health and well-being of patients and users. Efficacy, identity, and purity are therefore the most important quality attributes applied to these products. To guarantee the required quality, the monitoring of the climate parameters of temperature (°C) and relative humidity (%RH) assume a key role in production and storage. There are also detailed requirements for this in directives and standards. To be able to meet the requirements of a wide range of measuring tasks, automated monitoring systems need to be implemented effectively at critical application areas in the pharma sector.

Objectives of climate monitoring

The raw materials and substances involved, and the end products, are very sensitive to the wrong climatic conditions, such as temperature and humidity. However, it is not only the drugs per se, or their constituents, that are at risk when stored outside the permissible temperature range, their storage containers or packaging are also affected.

- Major fluctuations in temperature can cause hairline cracks in ampoules and glass containers.
- This can lead to contaminations and even loss of sterility.
- Too humid storage conditions can negatvely influence the quality of drugs.
- Damp packaging or blurred and illegible labelling can also occur

International Regulatory Guidelines Revolving Pharma QA & QC	
Regulatory Body	**Standards Established**
▪ World Health Organization (WHO)	Good Manufacturing Practice (GMP)
▪ German Ordinance on the Manufacture of Medicinal Products and Active Pharmaceutical Ingredients	Requirements of AMWHV
▪ EU guidelines	Good Storage Practice (GSP)
▪ US FDA regarding	Current Good Manufacturing Practice (cGMP) from 21 CFR Part 211

- Development of mould on and in boxes are also possible.

For these reasons, constant monitoring, and documentation of the prevailing climate parameters in the relevant areas are indispensable and they are controlled by a wide range of regulations and legal requirements. This means that sophisticated climate monitoring is an enormously important component of the whole product development and distribution process – starting in the research laboratory, via production and storage, through to the final transport of the goods. also, rooms are also very sensitive in this connection. Here, quality assurance must involve permanent monitoring and documentation of the differential pressure, air flow velocity and quantity of particles in the air, in addition to the temperature and relative humidity parameters. The exclusion of financial losses is another very important reason for permanent monitoring of the right environmental conditions. It is not possible to exclude all risks through monitoring, but they can be reduced to a manageable and safe level. Most importantly, in any pharma division regular internal and external audits are conducted, during which one can show the real time data, as per compliance and the previous data can be retrieved from the system whenever required.

Current measuring technologies

There are different ways to measure important climate parameters. Measuring values can be recorded using mechanical, analogue, or digital methods. This process can be carried out manually or in a semi-automated or fully automated way. The technology which is used in each individual case very much depends on the sector and the directives in force. In some sectors, electronic measurement methods are prescribed by law, and rightly so for several reasons: Analog measuring instruments already have a high potential for errors, unacceptable ranges of fluctuation etc & thus cannot be used for extremely critical processes and areas of application – particularly as documentation which is carried out manually also has an enormous potential for errors and tampering.

Measurement Technology- Features & Use Cases			
Measurement Technology	**Analogue**	**Mechanical**	**Digital**
Parameters			
Mode of operation	Manual	Semi-Automatic	Automatic
Error Potential	Very high	Comparably low	Very low
Fluctuation	Very high	Comparably low	Very low
Critical use cases	Cannot be used	Cannot be used	Can be used
Digital Communication	N/A	N/A	▪ Short Message Service (SMS) ▪ Emails

With semi-automated methods, such as electronic handheld measuring instruments or data loggers, measurement is carried out digitally and automatically. However, manual steps are still necessary to analyse & document the data, which is again prone to human errors, high personnel expenditure, delayed reaction time & several other issues. Only automated systems can restrain such non compliances. All the options described so far measure and document measurement data, but they do not monitor them. Automated climate monitoring systems regularly monitor the parameters, automatic transmit and document the measuring values & even provide alarms when there is a violation of limit values even at critical times of the day. The alarm notification itself can be provided either via acoustic or visual signals, but also by sending messages via Short Message Service (SMS) or emails. In addition, all the conditions that jeopardize the reliable operation of the system including for example connection problems, low battery statuses or an inadequate mobile phone network can be detected, reported, and thus immediately rectified.

Features of Automated Data Monitoring system

Apart from the alarm indicators & monitoring of values these systems feature data transmission & report generation as their key highlights. Transmission of the measuring values from the measuring point to the database is possible both via radio and a wired connection. Many systems combine both these possibilities, which means the technology has a high level of flexibility and readiness for use.

This process involving the automated transmission and analysis of measuring

values prevents all errors which may occur due to the human factor in manual readouts and the interpretation of values. Furthermore, any tampering with the values is virtually ruled out. This is ensured by automatic documentation and reporting which is set up individually. This means that reports are generated from the raw data and even directly dispatched, without there being any contribution from a user.

Other Important aspects of data monitoring systems

A validation is required everywhere where documented proof must be provided that a process or system meets previously specified requirements in a reproducible way. For the pharmaceutical sector, this means that a measurement system is tested within the operational environment and together with all the influences that effect the system and must comply with all the prescribed directives and laws in the process, such as adherence to 21 CFR Part 11.

Another important aspect is the data security and authorization access. This involves ensuring through detailed user management that employees and their authorizations can be individually configured. There is therefore a guarantee that individual system contents are only used by authorized employees.

Furthermore, control is crucial: systems must have the possibility of noting every movement within a system and assigning it to an employee. This may for example involve login/logout, setting limit values or the acknowledgement of alarms. To achieve this, there are several methods such as the so-called audit trail, along with electronic signatures. Every action is unambiguously assigned to one person by these mechanisms.

Testo Saveris – A Solution for the Pharma QA & QC Industry

Very large number of functions and methods must be implemented in a system to enable all the requirements to be met. Thus, a system must offer both reliability and flexibility. Testo Saveris data monitoring system meets such needs in every aspect. It consists of a central base unit that communicates, through a combination of radio and wired network, to multiple probes installed at different areas of application. Multiple data storage, data integrity, continued operation along

with a distinctive reporting system and indicative alarm features makes testo system a trustworthy component of the pharma sector. ■

Author

Roland Elsässer
Manager Product & Application
Testo SE & Co. KGaA

High-End Titration System to Increase Productivity and Efficiency in the Pharmaceutical Laboratory

High-end titration systems provide users with the possibility to consolidate their wet chemical analysis on a universal platform. With this comes the flexibility to expand and customize platform as your business grows.

Flexibility:

laboratories nowadays need flexibility to respond to new challenges as they arise. Hence, the platform can be abled to expand at any time to provide additional capacity for new applications and/or higher sample throughput. This is done by adding the required hardware, e.g., another titration module, another workstation, or even a robotic autosampler to the existing platform.

Multitasking:

The implementing newer Karl Fisher titration systems such as OMNIS can boost efficiency with the possibility to perform several tasks in parallel. Here is an example: While a titration is performed in a

sample on one workstation of the OMNIS Sample Robot, the next sample is already being prepared on another workstation. A third and fourth workstation may be used to further integrate the same application or to perform different ones – simultaneously.

Automation:

Increased reproducibility and faster results, the modular design allows you not only to expand the titration system according to your needs but also to reduce the manual workload in your lab by adding automated sample preparation steps such as pipetting, homogenizing and diluting. Simultaneous automation of Potentiometric titration and Karl Fischer using single OMNIS Sample Robot with 2 workstations.

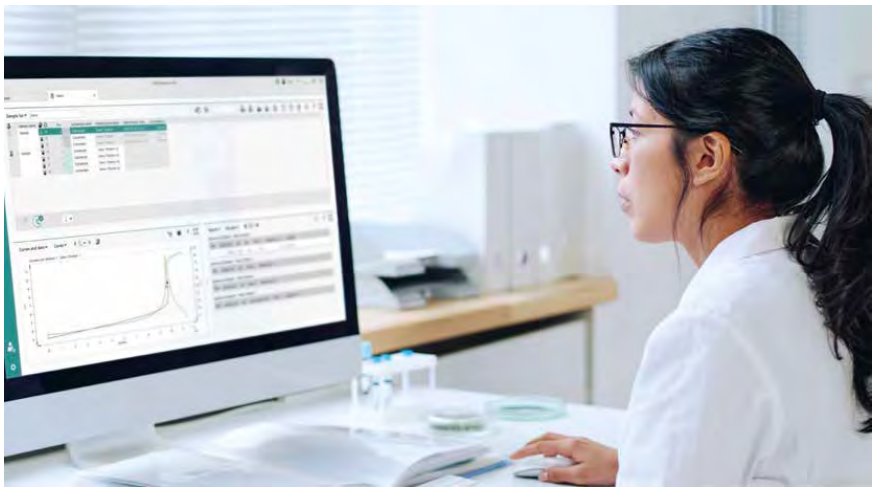
KF Titrator, a fully integrated solution for water content determination with volumetric Karl Fischer titration. Determining water in samples has never been more convenient, safer, and easier. With OMNIS system, Karl Fischer titration is safer than ever. Contact with toxic reagents and solvents is eliminated. No contact during reagent exchange thanks to 3S Liquid Adapter. All reagents contained in a closed system. Used reagent is discarded automatically and automatic titration cell filling and emptying.

Contact-free reagent exchange:

Exchange reagent bottles safely with high end titration systems. One, no longer needs to open bottles with hazardous liquids. Simply snap the Liquid Adapter onto the cap of the reagent bottle. This closed handling system establishes a safe connection between the reagent and your OMNIS Titrator preventing accidental contact with hazardous liquids.

Straightforward upgradation on field:

The modularity of titration systems includes the possibility to increase sample throughput by automation. Hence, throughput can be pushed in increments from 50 to 125 to 175 samples based on the x-y-z system of the OMNIS Sample Robot. Peak performance is defined by four titrations performed simultaneously at four workstations to analyze 175 samples completely unattended.



Software:

A novel titration system should provide a construction kit of discrete functional steps, which can be freely combined and used repeatedly. Thus, customized operating procedures can be built block by block with the least possible effort.

Measuring a particular sample may require several different methods to be performed in a specific order. If whole series of samples must be analyzed, maintaining an overview becomes a challenge. Not so with OMNIS: Users can open the sample profile at any time to see, which samples (and parameters) have already been analyzed and which are next.

A system enabled with Client/Server will help you to increase the efficiency of your laboratory enabling straightforward collaboration and managing data, instruments, SOPs, and users centrally.

The central Audit Trail of OMNIS titration can provide complete documentation of each client's activities. The secure database and user administration are other features that make working in an OMNIS Client/Server network compliant with regulations such as FDA 21 CFR Part 11 and EudraLex, Volume 4, Annex 11.

Highlights of a High-End Karl Fischer Titration System

- Five manual or four fully automated titrations can be performed at the same time for a higher throughput
- New patented system for safe and contact-free reagent exchange
- Resolution of up to 100,000 steps for higher precision
- Modular design for more flexibility
- Modern and intuitive OMNIS software for reliable, reproducible, and traceable results
- Compliance with FDA Regulation 21 CFR Part 11 and EudraLex, Volume 4, Annex 11. ■

Author

Dr. Thyagarajan S.
Product Manager – Titration
Metrohm India Pvt. Ltd.

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Turbidity measurements and technology used in Pharmaceuticals and TOC

Why to do Turbidity Measurements?

Turbidity measurements are done to get an idea about the contaminants and nano suspension present. For the drugs like cephalosporin and carbapenem which are used to treat bacterial infections, put to turbidity tests to get guidance, and take necessary corrective and preventive measures in the production. The turbidity limit for these drugs is 6 NTU. In many pharmaceutical industries production equipment like glass reactors and metal parts of machines are thoroughly washed and cleaned with high purity water.

Turbidity and TOC (Total Organic carbon) of such water before and after cleaning is done to check the contaminants present and for cleanliness of the equipment. Team proceeds with the production only If these parameters are within the prescribed limit. Turbidity and TOC of process water used in formulations is also tested and FDA norms for such water are very strict. For turbidity it must be

below 0.2NTU and for TOC less than 10ppb for production of some drugs.

Modern Nephelometers

Modern Nephelometers are used for detecting turbidity of such samples and these are designed as per two methods, ISO 7027, and EPA 180.1. Method ISO 7027 uses red LED light source with 860nm filter and EPA 180.1 uses tungsten lamp with filter 507nm.

These Nephelometers are specially equipped with four detectors and are well suitable for detecting a trace level turbidity below 0.1 NTU. The technology uses arrangement of four detectors around the sample cell, one detector at 180° which is measuring direct transmittance of light passing through the sample cell and the other three detectors observing scattered light from the sample cell which are arranged at 90°, 45° forward and 45° backward. The two detectors at 45° forward and 45° backward are very useful for checking trace level suspension in the sample.

ISO 7027 & EPA 180.1 methods

The method ISO 7027 is found to be more reliable comparing to method EPA 180.1.

Modern Nephelometers		
	ISO 7027	**EPA 180.1**
Light Source	Red LED	Tungsten bulb
Commercial variations	N/A	Halogen gas filled lamps
Light source lifespan	Comparably high	Comparably low
Light Intensity variation	Uniform intensity	Intensity variations observed
Filter (wavelength, nm)	860 nm	507 nm
Trace turbidity level	below 0.1 NTU	below 0.1 NTU
Reliability	Highly reliable	Comparably less

The reason for this found to be light source, red LED emits uniform and stable intensity light comparing to tungsten lamp where variation in intensity of light is observed. Another advantage of red LED light over tungsten lamp is that red LED is far more lasting comparing to tungsten lamp. Some manufacturers of EPA 180.1 method turbidity meters use halogen gas filled lamps to somewhat achieve uniform intensity of light and to garner a commercial advantage photometric features like absorbance, transmittance and concentration are added to make it two in one instrument, turbidity as well as photometer.

PPB Level TOC analysis as per USP 643 method

For ppb level TOC analysis as per USP 643 method, instrument with UV light and conductivity detector is used. The technique involves measurement of conductivity before and after UV radiation. UV light breaks the organic content present in the water and converts it to CO_2 which gets dissolved in water resulting increase in conductivity of water. The difference in conductivity gives the TOC present. The Technique is so superior with very low maintenance cost that many manufacturers use it in online TOC instruments for reliable monitoring of trace level TOC in process water used for production of drugs. UV technology is more suitable than the catalytic oxidation with NDIR (non-dispersive infrared) detector for such low level of TOC analysis. NDIR detector is found to be more reliable in high range where gas phase of CO_2 is measured with the use of limited trace amount of water sample. ■

Author

Srinivas Botla
Manager, Product Applications
Savant Instruments Private Limited

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