August 2024

CuriRx
Innovative therapeutics for cure

Newsletter

Highlights

Words from Indu Javeri, Founder, CEO

Dear Valued Clients,

As the Founder and CEO of CuriRx, Inc., I want to take a moment to express my deepest gratitude for your continued trust and partnership. Your unwavering support and collaboration have been instrumental in our journey, and we are truly honored to serve you.

We are thankful for the trust you place in us to deliver innovative solutions that meet your needs. Your confidence in our capabilities fuels our commitment to excellence and drives us to push the boundaries of what is possible in our industry.

About CuriRx Video

Celebrating Our Achievements Together

This year has been remarkable, filled with milestones and achievements that we could not have reached without your support. Your feedback and insights have been invaluable, helping us to refine our processes and enhance our services. Together, we have navigated challenges, celebrated successes, and continued to strengthen our partnership.

Looking Forward to the Future

As we continue this journey, we are excited about the opportunities that lie ahead. We are committed to maintaining the highest standards of quality and innovation, ensuring that we exceed your expectations.

Our partnership with you is at the heart of our mission, and we look forward to many more years of successful collaboration.

Thank you once again for your trust, support, and partnership.

Thank you,
Indu Javeri

Feature

Overcoming Stability Challenges in Lyophilization through Quality by Design Approach

Lyophilization, or freeze-drying, addresses stability challenges associated with complex APIs, biologics, microbiomes, gene therapies, viral vectors, liposomes, and nanoparticles.

This process is particularly advantageous for parenteral drug developers, as it converts unstable liquids into stable powders suitable for injection, enhancing packaging and transfer as a finished drug product.

Additionally, lyophilization is employed to produce stable intermediates in drug development, particularly for hydrolytically unstable components like PLGA microparticles or fragile APIs, extending their shelf life.

For instance, APIs undergoing high-energy media milling may be lyophilized before incorporation into oral solid dosage forms. While lyophilization offers substantial benefits and commercial viability, it also introduces complex formulation processes and manufacturing challenges. Each product, especially those involving nanoparticles, microparticles, liposomes, or microbiomes, requires customization and extensive lyophilization cycle development.

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Feature Article*...continued from page 1*

What are the Challenges in Drug Product Development?

Quality by Design (QbD) principles are integral starting from the outset of product and process development, guided by the target product profile and desired quality attributes.

In developing injectable lyophilized products, quality is a critical component in every step of the lyophilization process, from development to technology transfer, scale-up, and GMP manufacturing.

Our focus is primarily on parenteral products—IV, IM, and subcutaneous. Many of these types of products encounter stability issues in liquid dosage forms, making lyophilization an attractive option for stabilization.

The desired quality attributes of a stable dosage form include maintaining chemical, physical, and functional stability. It is important to ensure the product remains within established specifications for its identity, strength, potency, quality, and purity.

Complex products often face challenges such as temperature fluctuations during transport, precise storage requirements, and physical handling during manufacturing, storage, and distribution. A properly executed lyophilization process enhances the stability of parenteral products, reduces contamination risks, and facilitates easier and safer handling, storage, and transportation.

The challenges of developing a consistent and scalable lyophilization process and mitigating these challenges relies on a thorough understanding of the product and process, identifying weaknesses and strengths, and incorporating quality through QbD principles.

CuriRx's new e-book explores these challenges and proposes mitigation strategies through a Quality by Design (QbD) approach.

Highlights of this e-book are:

- Case studies of lyophilization cycle development
- Lyophilization of complex pharmaceuticals, challenges, and the Quality by Design approach
- Lyophilization cycle development of technology transfer, scale-up, and GMP manufacturing

Download e-book

Industry News

2024: Trends Shaping the Future of Pharma

Unveiling the dynamics of pharmaceutical outsourcing.

Article by Tim Wright, Editor, Contract Pharma02.01.24

In the ever-evolving landscape of pharmaceuticals, companies are increasingly turning to outsourcing as a strategic approach to navigate challenges and capitalize on opportunities. As we move into 2024, the pharmaceutical outsourcing landscape is undergoing a paradigm shift. The realm of pharma outsourcing is witnessing transformative trends that are reshaping the industry. Let's delve into some of the key dynamics defining the future of pharmaceutical outsourcing.

1. Accelerated shift towards CDMOs

Pharmaceutical and biotech companies are embracing contract development and manufacturing organizations (CDMOs) at an unprecedented rate. This shift is fueled by the desire to streamline operations, leverage specialized expertise, and expedite the drug development process. CDMOs offer a one-stop solution, encompassing everything from early-stage development to commercial manufacturing.

2. Biologics boom

The era of biologics and biosimilars is upon us, and outsourcing has become a cornerstone of this burgeoning field. The inherent complexity of biologics necessitates advanced technologies and specialized facilities, making CDMOs the go-to partners for companies venturing into this realm. The outsourcing of biologics development is not merely a trend—it's a strategic imperative.

3. Flexibility and agility

Pharmaceutical outsourcing is no longer just about cost savings; it's about adaptability. Companies are seeking partners that offer flexible and modular manufacturing solutions. The ability to scale production volumes up or down swiftly and efficiently has become a competitive advantage in a dynamic market where demand fluctuations are the norm.

4. Cutting-edge technologies redefining manufacturing

The adoption of cutting-edge technologies is transforming the manufacturing landscape. Continuous manufacturing, data analytics, and automation are no longer buzzwords but integral components of outsourcing partnerships. Companies are seeking CDMOs with advanced capabilities to enhance efficiency, reduce costs, and ensure regulatory compliance.

5. Collaborative ecosystems

The traditional client-vendor relationship is evolving into collaborative ecosystems. Strategic partnerships and collaborations between pharmaceutical companies and CDMOs are fostering innovation, resource-sharing, and shared success. This collaborative approach is proving to be instrumental in navigating the complexities of drug development.

6. Regulatory compliance as a cornerstone

Regulatory compliance remains a non-negotiable aspect of pharmaceutical outsourcing. CDMOs are placing a strong emphasis on ensuring that their operations adhere to the stringent regulatory standards set by health authorities globally. A commitment to compliance is not just a regulatory requirement but a testament to the reliability of outsourcing partners.

7. Cell and gene therapy revolution

The emergence of cell and gene therapies is reshaping the pharmaceutical landscape, and outsourcing is playing a pivotal role in this revolution. CDMOs equipped with the expertise and infrastructure to handle the unique challenges of these therapies are in high demand. Outsourcing is facilitating the translation of groundbreaking research into viable therapies.

As companies seek to navigate complexities, drive innovation, and bring therapies to market efficiently, strategic partnerships with CDMOs are proving to be indispensable. The trends outlined above are not fleeting; they are the pillars upon which the future of pharmaceutical outsourcing is being built. In this dynamic environment, adaptability and collaboration will be the keys to success for both pharmaceutical companies and their outsourcing partners.

Project Spotlight

CuriRx was engaged by IAVI/Rockefeller to develop two high concentration anti-AIDs antibody formulations at 200 mg/ml individually and then a combined and co-formulated antibody. The project was funded by Gates Foundation and managed by IAVI.

CuriRx also developed new analytical methods (SEC, RP and CEX-HPLC) for the co-formulated antibodies and IAVI published the following paper based on the work performed at CuriRx.

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Project Highlights

Project Title: Develop high concentration formulation for two broadly neutralizing anti-AID antibodies each individually and co-formulate at 400 mg/vial.

Period of Performance: 2 years

Brief Description of Project Scope and Customer Expectations

Customer Expectations: Subcutaneously administration, low viscosity, isotonic solution with pH range from 5-7.

Brief Description of Approach and Performance

The project was successfully completed, with the formulation development at 200 mg/mL with desired injectability/viscosity attributes, a 12-month non-GMP stability study, a formulation process development for transfer to a GMP site, and co-formulation resulting in client publishing the characterization methods developed at CuriRx for combined antibodies in one vial for purity, quantity and consistency.

*Characterization of Co-Formulated High-Concentration Broadly Neutralizing Anti-HIV-1 Monoclonal Antibodies for Subcutaneous Administration by Vaneet K. Sharma 1,†,Bijay Misra 2,†,Kevin T. McManus 3,Sreenivas Avula 1,Kaliappanadar Nellaiappan 2,Marina Caskey 4,Jill Horowitz 4,Michel C. Nussenzweig 4,5,Michael S. Seaman 3,Indu Javeri 2 and Antu K. Dey 1,**

Antibodies 2020, 9(3), 36; https://doi.org/10.3390/antib9030036
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7551838/

Partial Client List

ModeX THERAPEUTICS an OPKO Health Company

uvaxbio

Takeda

www.curirx.com • info@curirx.com • 205 Lowell St. Suite 1C Wilmington, MA 01887 •

Human Resources

New Employees

- **Ayman Ismail:** *Senior Scientist – Downstream Bioprocessing*
- **Christopher Soto:** *Senior IT Support Engineer*
- **Patricia Lever:** *Director of Business Development*
- **Travis Smith:** *Scientist II – Analytical Testing*
- **Thomas Williams:** *QA Specialist*
- **Ryan Toffey:** *Senior Controller*

Workplace Culture

At CuriRx, we actively implement principles to create an exceptional workplace culture that fosters growth, innovation, and employee satisfaction. Our approach encompasses several key elements (**1) Onboarding Experience (2) Smart Goals (3) Communicating Effectively and (4) Fostering a Positive Environment.**

We recognize the importance of first impressions and ensure new joiners receive an outstanding and comprehensive, Onboarding Experience. This helps new employees seamlessly integrate into our team, which allows them to embrace our positive work culture from the very first day.

Then using our Smart Goals framework, we align individuals and teams with achievable Smart Goals that align with our corporate objectives to individual contributions to ensure we are all moving in the same direction.

Once goals are set, Communicating Effectively becomes critical to our success as an organization, it helps maintain a cohesive and collaborative workplace. Ways we achieve this is through promoting an open-door policy across the organization, conducting weekly companywide team meetings, one-on-ones, and utilize collaboration tools to keep everyone in the loop. This transparency helps us address any issues promptly and maintain a cohesive workflow.

As an HR leader you should lead by example: do your best to bring joy and happiness to the workplace every day! Walk the talk! Demonstrate the values and work ethics we expect from our employees. By demonstrating commitment, integrity, and a positive attitude, you inspire the entire organization to uphold these standards. Positive attitude is contagious!

Finally, Foster a Positive Environment: We believe in nurturing a supportive and inclusive culture. At CuriRx, challenges are viewed as opportunities for growth. We encourage continuous learning, innovation, and collaboration, ensuring that every team member feels valued and empowered.

By embracing these principles, CuriRx not only creates a productive and positive work environment but also attracts top talent and earns the trust of our clients. We are committed to building a culture of excellence and delivering outstanding Quality results for our clients!

Co-op Program

At CuriRx, part of our mission is our commitment to future generations. We are partnered with Northeastern University (NEU) for their Cooperative Education Program (Co-op).

Northeastern University's experiential learning approach enhances on-campus study with real-world experience through full-time employment at locations worldwide. Through co-op, students alternate periods of academic courses with periods of employment in positions related to their academic or career interests. This combination provides an integrated learning experience that enhances both in-class studies and career development.

We host two waves of amazing students throughout the year, each lasting six months: Wave One - January to June and Wave Two - July to December

Our current Co-ops are:

Formulation Group: Lab Assistant Interns
- Matthew (Matt) Murphy
- Abigail (Abby) McGair

Analytical Group: Lab Assistant Interns
- Sunay Patel
- Nicholas (Nick) Moniak

Quality Assurance Group: Quality Assurance Co-ops
- Ankita Narendra Kshatriya
- Sanyukta Shrikant Manjurkar

Bioprocess Group: Lab Assistant Interns
- Akash Awasarmal
- Vinay Viswanath

Generative AI: Generative AI Data Science/Co-op
- Tanmay Kumar Patel

Supply Chain: Logistics & Inventory Co-op
- Fenil Patel

Services Highlights

Formulations

Formulation Studies
- Small molecule: Stability Fingerprinting®
- Biologics: Solubility Fingerprinting®
- Identify stability-indicating assay
- Screening (buffers, stabilizers, etc)

Lyophilization
- Instrumentation: LyoStar II-FTS Lyophilizer (2)
- Facilitate global transport and storage
- Withstand adverse environmental challenges
- Enable to move through clinical trials expeditiously

Nanotechnology
- Deliver types: Injectable, Oral, Topical
- Size
- Encapsulation
- Loading efficiency
- Drug release profiles

Learn More

Bioprocessing

Cell Line and Strain Development
- GS and DHFR expression systems
- CHO (ExpiCHO, CHOK1, CHOZN)
- E.coli, Yeast, S. cerevisiae, Pichia pastoris
- High throughput screening for high biomass/titer producer
- Single cell isolation
- Clonality assessment
- Analytical confirmation

Upstream Process Development
- Media & feed screening, development, and optimization
- Fed-batch/ continuous bioreactor conditions development
- Recovery and separation development
- Cell disruption and protein refolding
- Process scale up and down
- Upstream process characterization

Downstream Process Development
- Resin screening
- Chromatography development and optimization
- Filtration (TFF and depth filters) development and sizing
- Bulk formulation development
- Viral clearance and inactivation steps development
- Downstream process characterization

Learn More

Analytical Service

CuriLytics®- CMC Analytical Support
- High Resolution Mass Spectrometry
- Orthogonal Approach
- Discovery and Targeted Proteomics
- Structural Characterization
- Purity/Product Related Impurities
- Physiochemical Properties
- Process Related Impurities

Analytical Testing Services
- Protein identification
- Peptide mapping
- Antibody/protein characterization
- Protein post-translational modifications
- Protein disulfide bond mapping
- Accurate mass measurement
- Protein aggregation
- HCP (host cell protein) analysis
- Protein quantitation analysis
- Protein glycosylation analysis
- Released glycan profiling

Quality Testing
- Quantification
- Verification
- Stability Testing

Learn More

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