ThermoFisher SCIENTIFIC

Rx SOFTGEL SOLUTIONS

FIND THE RIGHT DOSAGE FORM TO SUIT YOUR MOLECULE

- API
- BIOLOGICS
- VIRAL VECTOR SERVICES
- EARLY & LATE PHASE DEVELOPMENT
- CLINICAL TRIAL SOLUTIONS
- LOGISTICS SERVICES
- COMMERCIAL MANUFACTURING

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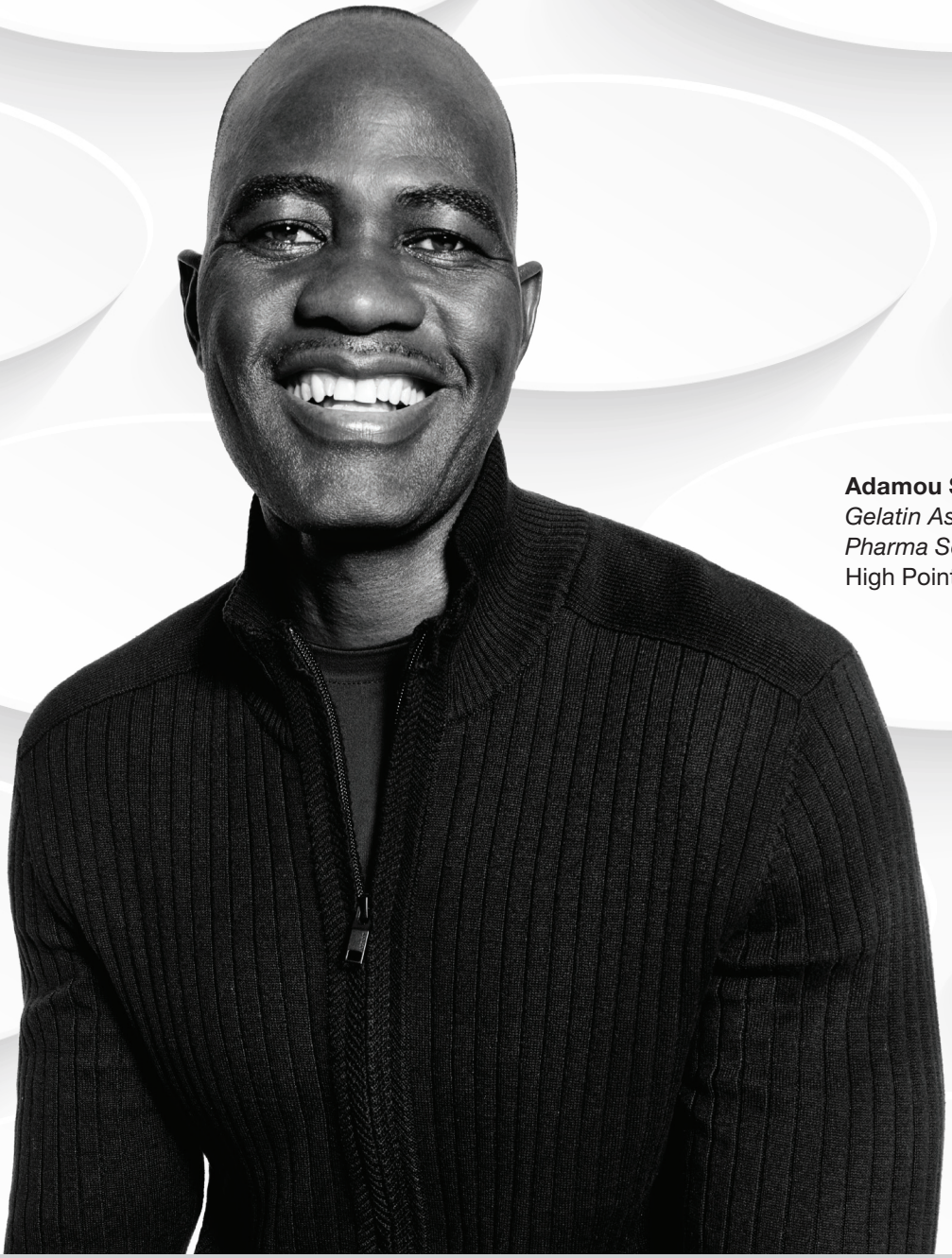

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HOW WASTED MATERIAL INSPIRED SAVING TIME AND MONEY.

When it comes to manufacturing softgel dosage forms, nobody knows more about operating the equipment that makes them than Adamou. He's relentless about finding new ways to make the manufacturing process more efficient. So, when he saw the amount of scrap material being produced during a specific manufacturing process, he was determined to find a way to decrease it. He enlisted the help of a team of experts who supported his cause and they worked after hours and weekends until they found a solution. The result is a new process that greatly reduces scrap, delivers savings to customers, and most importantly, helps to lower the cost of medicines for the patients who need them.

A flexible, innovative partner for your Rx softgel needs

The outsourced Rx softgel market is estimated at $810 million. With a lot of competition between CDMOs in both the United States and Europe, choosing the right partner to develop your Rx softgel drug can be a difficult decision. Whether your product has solubility issues—like 70% of drugs in development—or requires abuse-deterrent technology, softgels may be the best formulation choice.

Thermo Fisher Scientific offers softgel development and manufacturing solutions for specialized Rx products including highly potent drugs, hormones, DEA-controlled substances (schedule I–III), and abuse-deterrent products.

We have the experience of formulation, analytical method, and process development plus the manufacture of clinical material across all phases and scale up to commercial manufacture. Our portfolio of proprietary gelatin technologies offers solutions to formulation issues, and our experience in formulating these technologies assists customers in finding the right dosage form to suit their needs.

"Very responsive team. Strong technical and problem-solving skills. The formulation and manufacturing team work very efficiently in trouble-shooting and provide excellent options for process improvements."

— Clinical-stage biopharmaceutical company, USA

Global network and capabilities

Softgel site network

Our softgel sites in High Point, North Carolina and Tilburg, Netherlands offer both development and commercial capabilities for softgel dosage forms, with a combined capacity of 10-12 billion softgels annually, supporting scale-up within one network. We also offer direct tech transfer expertise, providing quick-to-market solutions for you and your product.

Our team boasts decades of experience in softgel manufacturing and assistance with regulatory affairs, and our team of more than 70 R&D employees work tirelessly to formulate robust products with proven stability. With more than 180 softgel patents in our portfolio and eight cutting-edge proprietary technologies, you can trust us to deliver the best solution for your market needs from development through commercial launch.

Proprietary technologies to suit your molecule and market needs

Solutions for geriatric/pediatric populations

The following softgel technologies provide effective solutions for geriatric/pediatric populations who may have trouble swallowing tablets and prevent overdosing.

Chewels® chewable gels are approved for pharmaceutical use and are ideal for pediatric and geriatric populations. They are also well-suited for people who find swallowing difficult and are looking for a convenient dosage form for administration.

With a soft chewable shell, LiquiSoft™ softgels are particularly suitable for liquid fills that require fast onset of action and or/buccal absorption. LiquiSoft softgels come in a variety of flavors that mask bad tastes and odors, adding to patient appeal.

Twist-offs can help reduce dosing errors observed with other liquid formulations by providing the exact amount of liquid needed in the capsule. Twist-offs are suitable for newborns and young infants and are also well-suited for dermatologic products.

Soft lozenges are a preferred dosing option for patients who have difficulty swallowing. Easy to administer to geriatric and pediatric populations and have a pleasant taste. Lozenges do not require water intake for administration. They can be formulated as sugar-free and are pharmaceutical grade.

Abuse-deterrent technology: Versatrol™

Versatrol™ controlled release softgels possess an innovative tamper-resistant technology, making them an excellent choice for abuse-deterrent formulation and/or preventing dose dumping. They are immune to injection, sniffing, crushing, or dissolving. The controlled release properties are never compromised.

Skip the coating with our Entericare® technology

Our EnteriCare® technology incorporates the enteric properties directly into the gelatin shell, replacing extra steps such as coating during the manufacturing process. This creates more consistent enteric behavior. EnteriCare products can be developed as transparent softgels, which creates a more appealing aesthetic quality compared to traditionally coated capsules.

Additional softgel solutions

Sofgels® technology is suitable for liquid formulations, applications requiring faster onset of action, low-dose products, and those with poor bioavailability that would benefit from a lipid system. These capsules are easy to swallow, and twist-off options are available.

Soflet® Gelcaps employ a gelatin-enrobing technology that makes tablets easier to swallow. A broad palette of colors and imprinting choices are available, including inline printing.

"Good technical expertise and know-how on softgel technology."

— Biotechnology company, USA

Regulatory services and support

Our regulatory affairs team in Tilburg, Netherlands provides unmatched support for clients during development/pre-approval and post-approval for dossier maintenance. Our experience with various regulatory bodies and close relationship with your drug's development team help you get to market quickly.

- Experience in regulatory affairs and procedures, with the ability to provide independent and optimal advice on the best regulatory strategy on a case-by-case basis
- Submission of the applications—as eCTD—to regulatory authorities, subsequent monitoring of the procedure, responding to regulatory queries, and the formal closing of the application procedure

Our offerings throughout development and pre-approval include:

- Support during product development following ICH, EMA, and FDA regulatory guidance
- Regulatory dossier compilation of Module 3 in compliance to current guidelines—writing and collecting documentation needed for the submission
- Guidance during the clinical study—e.g., selection of reference product, preparation of IND, IMPD, and clinical trial applications
- Clinical trial labelling, packaging, and distribution—via Thermo Fisher Clinical Services℠
- Guidance throughout the clinical and bioequivalence study process

Our regulatory affairs assistance does not end at drug approval. We offer post-approval compliance review of dossiers according to ICH, EMA, and FDA legislation, as well as maintenance throughout the dossier lifecycle, such as variations and renewal applications submitted to the competent authorities.

Harness the power of an integrated network with Quick to Care™

Patheon's Quick to Care™ suite of services delivers a streamlined drug development program. This offering combines your drug substance and drug product development, clinical manufacturing, forecasting, demand planning, and clinical trial supply execution into a single solution to accelerate your discovery to proof of concept. Save time and money on your development journey with:

- Comprehensive program management with a single point of contact
- Scientific insight to speed every step
- Assurance of supply
- Simplified contract and administration
- Optimized tech transfers

Quick to Care™ Program

- Clinical Supply Planning
- Viral Vector Development & Manufacturing
- Drug Substance Development & Manufacturing
- Drug Product Development & Manufacturing
- Clinical Trial Packaging & Labeling
- Clinical Material Distribution & Logistics
- Transportation Management
- Commercial Manufacturing & Packaging

Clinical supply services

Once your softgel is ready for clinical trials, we can assist with the logistics. Whether you need primary or secondary packaging of your clinical drug, storage, distribution, logistics, cold chain management, or comparator and ancillary sourcing, our global team can meet the needs of every trial regardless of size, phase or therapeutic area. We also offer import/export services, including Importer of Record (IOR) capability in more than 25 countries to date, and best-in-class direct-to-patient services.

We are committed to delivering the highest possible value while ensuring adherence to the highest level of quality, performance, reliability and sustainability standards.

180
softgel patents

46
Rx softgel projects started since 2018

Learn more about our softgel development and manufacturing solutions. Contact us today.

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Published 04/2021

ThermoFisher SCIENTIFIC