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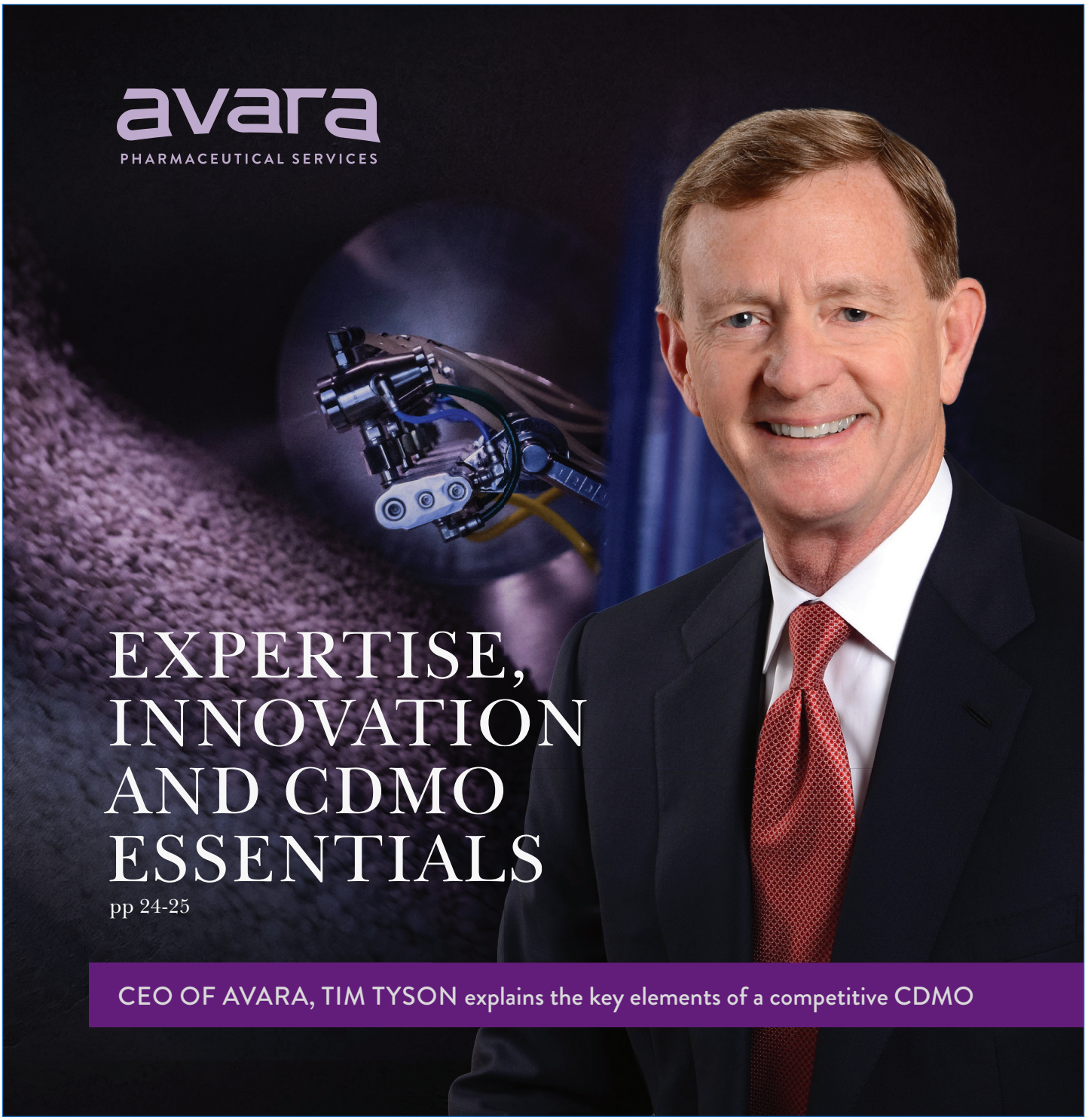

EXPERTISE, INNOVATION AND CDMO ESSENTIALS

pp 24-25

CEO OF AVARA, TIM TYSON explains the key elements of a competitive CDMO

BIOPROCESSING
Reducing upstream scale-up risks with QbD and HSPC-GT: meeting an industry challenge

INTELLECTUAL PROPERTY
Inorganics spark rise in pharmaceutical innovation

MANUFACTURING EQUIPMENT
Drying, granulating and coating, plus process optimisation with dynamic powder characterisation

EXPERTISE, INNOVATION AND CDMO ESSENTIALS

A CDMO, or contract development and manufacturing organization, is no longer expected to simply manufacture

In the highly competitive pharmaceutical marketplace, a CDMO is not only expected to demonstrate the ability to deliver on time, in full—its products must also maintain the highest level of quality on all fronts of the supply chain. As a result of this emphasis on constantly improving, CDMOs are becoming crucial in a collaborative sense. These collaborations are often expressed through flexible deal structuring and strategic partnerships. In order to stand out from like organizations, a proactive CDMO must position itself as innovative and an expert in their offerings to gain a true competitive advantage.

TRANSITIONING PAST THE TRADITIONAL

The traditional CMO or contract manufacturing organization, gave way to the CDMO—emphasis on development— caused by a reverse integration into the value chain. What has followed is a plethora of rapid acquisitions and internal advancements by companies, largely taking place over the last 5 - 10 years. These changes were made to capture an increased market share and to provide a more fully integrated service to potential customers, including big pharma.The change in business model has been driven by significant rationalization in the pharmaceutical industry in both Manufacturing and R&D caused by significant excess capacity and a focus on reducing operating expenses and making previous fixed costs, variable. Pharmaceutical customers are looking for integrated providers that can provide an integrated service with technical expertise, a long-term commitment to quality/compliance at a competitive cost. The ultimate objective is to deliver speed to market and to assure a continuity of supply.

CREATING COMPETITIVE ADVANTAGE

CDMOs that wish to serve this type of customer must prove to clients that they are able to tailor their offerings to meet individual needs. The importance of flexible contracts, the ability to respond to demands rapidly, and to continuously deliver on all commitments is key for any CDMO looking to emerge as a long term, sustainable, competitive supplier. Customers are increasingly looking for global supply chain management capabilities and security of supply regardless of location, which means tackling regulatory demands on all fronts and in all regions.

As globalization becomes the norm, transparency has also become critical. An environment that fosters open communication is perhaps the main feature of any successful partnership, especially in this capacity. In spite of increased restrictions on importing raw materials, intermediates, active ingredients, and products in general, a CDMO with a proven track record of supply chain security and effective supply chain management both on an international and local level will come out on top. This cost pressure and complexity has increased, especially as serialization emerges as the next crucial component of drug development and manufacturing. A fully robust and operational Lean Six Sigma process is also essential to meet the evolving market expectations.

The CDMO that is proactive on this front will demonstrate technical expertise, process discipline and innovation capabilities, which customers are so often seeking in partnerships. It is necessary to invest continuously in improvements internally to create the advantage provided via innovation. In particular, technologies that support highly potent compounds, controlled substances or poorly soluble drug substance processing, formulation, and packaging are of interest. The greater the technological benefit, the greater the potential to solve problems and therefore develop a stronger partnership and leverage a greater profit share. Formulation development, clinical trial supply, process scale-up and of course, tech transfer will remain crucial beyond 2017, specifically for customers looking for integrated partners who can provide the capabilities that are needed to deliver future pharmaceutical products into the market.

COLLABORATION IS CRUCIAL

At Avara, we understand and recognize the importance of establishing and maintaining effective relationships and partnerships, and providing world class technical capabilities and experise. We are committed to working closely with our customers to provide API manufacturing (including highly energetic chemistry), bulk drug formulation, finished dose and primary/secondary packaging solutions (including for products that require high containment) tailored to their specific needs for solid dosage drugs. We are totally focused on providing an unsurpassed level of customer service dedicated to the need of our customers. We believe in and are committed to an on time, in full delivery of products we manufacture that meet all regulatory requirements and customer expectations—this is the hallmark of our customer service.

Although our company is relatively new, our people have extensive experience in the pharmaceutical industry on both the CDMO and pharmaceutical company sides. Avara has extensive experience supplying the US and international markets. We have a first-class safety, health and environmental record, Fast-to-Transfer and Rapid Change Over Capabilities, and have implemented an Operational Excellence and Compliance Oriented Program developed using Lean Six Sigma methodologies. As a result, Avara brings a wealth of process and industry knowledge and expertise in

supply chain management, process and formulation development, commercialization, product launch and technical transfer to bear on customer projects, facilitating the rapid, cost-effective development, manufacture and delivery of advanced medicines.

MEET AVARA PHARMACEUTICAL SERVICES

Avara Pharmaceutical Services is a world-class contract development and manufacturing organization. Avara provides API and bulk drug formulation and manufacturing as well as primary and secondary packaging services for solid dose drugs, including highly potent compounds. Our manufacturing technologies include granulation, coating, blending, encapsulation, compression and drying of tablets and capsules.

Led by a team of industry experts with extensive experience managing manufacturing infrastructures worldwide, Avara is focused on quality, compliance, customer service and delivering on time and in-full. With our deep understanding of the industry, world-class contract manufacturing and technical services and broad knowledge and expertise in supply chain management, commercialization, product launch and technical transfer, Avara sustains exemplary levels of product quality and regulatory compliance and consistently exceeds customer expectations

- Avara facilities have produced a number of blockbuster brands and transitioned several products to generic status
- Proven track record in process development, scale-up, validation and commercialization of NCEs and generic APIs
- Large-volume processing (direct compression, high-shear compression, capsule filling) of 1,000-2,000 million units per year
- World Class Customer Service, with a customer service satisfaction level > 99% for more than 5 years
- Exceptional Regulatory Compliance Track Record
- Lean Organization and Structure
- Fast-to-Transfer & Rapid Change Over for proven technology transfer and product launches
- Fair and Competitive Pricing
- Successful application of Lean Six Sigma tools to improve cost while sustaining compliance and supply
- Leadership team with extensive experience in international supply chain management

"Avara sustains exemplary levels of product quality and regulatory compliance which regularly exceeds customer expectations."

AVARA PHARMACEUTICAL SERVICES: A NEW COMPANY WITH VETERAN LEADERSHIP

Headed by industry veteran Tim Tyson, previously CEO and Chairman of Aptuit and President of GSK's Global Manufacturing and Supply division, Avara Pharmaceutical Services was created to meet current and future demand in the pharmaceutical industry for high-caliber contract development and manufacturing services.

Avara is addressing current market demands beyond superior quality and on-time delivery by leveraging manufacturing excellence and a definitive customer focus grounded in the mutual mission for saving and enhancing human life.

Having served as both a global head of manufacturing and supply for a big pharma and the Chairman and CEO of a leading CDMO, Tim Tyson brings a unique perspective to Avara. In his 35-plus year career, he has negotiated complex multi-billion dollar mergers and acquisitions, led major turnarounds that have fueled growth and value and, most significantly, been instrumental in bringing more than 50 lifesaving and life improving medicines to the market.

Under his direction, Avara will build on the strong foundation of its employee knowledge base and capabilities by leveraging their deep understanding of the pharmaceutical industry combined with the implementation of outsourcing and manufacturing best practices and through acquisitions of complementary businesses.

FOR MORE INFORMATION

Tim Tyson
CEO and Chairman
Avara Pharmaceutical Services