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Assessing Formulation Development Options

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Assessing
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OraVescent[®]
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Greater Oral
Transmucosal
Delivery

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Senopsys

SENOPSYS LLC: DEDICATED TO THE DEVELOPMENT OF PALATABLE PHARMACEUTICALS

Senopsys is a specialty services company on a mission to improve medication compliance and health outcomes through the development of patient-accepted medications. Senopsys partners with pharmaceutical, biotechnology, and drug delivery companies to optimize the sensory characteristics of medications. The company uses its proprietary FlavorMetricsSM assessment and FlavorOptSM development tools to assess the suitability of novel oral dosage forms and delivery technologies, improve the palatability of drug products, and develop new formulation systems for investigational and approved drugs. *Drug Delivery Technology* recently interviewed Jeff Worthington, Founder and President of Senopsys LLC, to discuss how his firm is collaborating with industry to develop palatable drug products.

Q: Senopsys is an interesting name – what does it mean?

A: Senopsys is derived from Sensory Optimization Systems, which is the core of what we do – namely help clients create products that can be differentiated based on patient-perceived sensory attributes.

Q: What is palatability, and why is it important?

A: Most dictionaries define palatable as “acceptable to the taste.” As consumers, we

have access to a seemingly limitless variety of foods and beverages representing a myriad of aromas, flavors, colors, textures, and mouth feels. Unlike consumers with their food choices, most patients do not look forward to taking their medicine, and they have comparatively modest expectations for the product. Most are looking for an “acceptable” tasting medicine – one that can be easily swallowed without pain or suffering. This translates to a drug product with moderate sensory characteristics – not too bitter; not too odorous; not too irritating; and not too hard, gritty, or sticky.

Most pharmaceuticals are developed and



**Mr. Jeff
Worthington**
Founder & President
Senopsys LLC

“Unfortunately, the importance of product aesthetics is generally underappreciated by the pharma industry relative to the underlying technology. This often leads to the launch of drugs that are unacceptable to many patients, despite their medical benefits. When medication compliance is compromised, health outcomes suffer, and drugs fail to realize their sales potential.”

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promoted exclusively on their medical benefits (superior efficacy, milder side effects, faster acting, or longer lasting), many of which have been enabled by advances in drug delivery technology. While these medical benefits are undeniably important, the product's aesthetics (appearance, aroma, flavor, texture, mouth feel, and ease-of-swallowing) can have a significant effect on patient compliance. Unfortunately, the importance of product aesthetics is generally underappreciated by the pharma industry relative to the underlying technology. This often leads to the launch of drugs that are unacceptable to many patients, despite their medical benefits. When medication compliance is compromised, health outcomes suffer, and drugs fail to realize their sales potential. At Senopsys, we are committed to changing this paradigm through the development of more palatable drug products.

Q: Okay but can palatability actually be measured?

A: Absolutely. Because pharma companies have generally underappreciated the importance of product aesthetics, knowledge of sensory science and flavor system development is diffuse compared to the consumer-packaged goods industries. In fact, there's a great deal of mythology in the pharma industry surrounding the development of palatable drug products. One of the biggest myths is that palatability cannot be measured. For this reason, Senopsys developed the FlavorMetrics Taste Assessment Tools to assist drug developers in addressing the key taste issues along the clinical and commercial development pathway. FlavorMetrics provides quantitative data to guide formulation development and support decision-making and consists of two modules. The FlavorMetrics Bitterness Profile is used to quantify the taste-masking challenge of APIs early in the development process and

assess the need for advanced taste-making technology. The FlavorMetrics Palatability Profile is used to measure the flavor quality of prototypes and competing products and provides a framework for supporting product optimization, reformulation, and launch decisions.

Q: Can you tell us more about Senopsys' development of palatable drug products?

A: In addition to providing sensory measurement services, Senopsys will work with clients to develop complete formulations for investigational and approved drugs. Senopsys' FlavorOpt sensory-directed formulation development approach was developed through decades of experience in the highly competitive food industry in which taste is paramount. We apply our extensive knowledge of sensory science, flavor construction, and excipient functionality to help clients

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develop formulations that are acceptable to patients. We have assembled a team of talented pharmaceutical sensory panelists and formulators who have worked on numerous over-the-counter and prescription drugs. This team has broad dosage form experience, including oral and intranasal liquids, powders, chewable and fast-dissolving tablets, oral films, and soft chews.

Q: Many in our industry believe the key to developing a palatable drug product is to select the most appropriate flavor. Is this not the case?

A: Another popular palatability myth is the notion that a product's flavor (orange, grape, chocolate, or mint) is the key determinant of patient acceptance. In actuality, a drug's palatability is much more complicated than its flavor. The key to developing palatable pharmaceuticals includes many factors, such as balancing the four basic tastes – sweet, sour, salty, and bitter – building blend

and body, extending the duration of the flavor system, and adding beneficial mouth feel factors.

These principles are all well understood by the food industry; we're not reinventing the wheel, rather translating best practices across traditional industry boundaries.

Q: Can you share with us your business model?

A: Senopsys is an objective and independent development partner. We do not sell ingredients or license technology and thus our objectives are always aligned with that of our clients – to develop patient-acceptable dosage forms. Our work is generally conducted on a fee-for-service basis, which most clients prefer. We also offer favorable intellectual property terms. For example, in the case of contract formulation development, the client obtains the rights to the resulting formulation for the particular study drug and dosage form combination and the right to use any embedded Senopsys intellectual property. This helps to ensure that the interests of both parties are aligned.

Q: At Senopsys, how do you measure success?

A: Senopsys will remain a privately held, specialty services company dedicated to the development of palatable drug products that meet the needs of diverse patient populations. We measure our success by the number and quality of drug products commercialized by our client development partners. We expect to continue our important work in pediatric formulation development. In addition, advances in drug delivery technology will continue to give rise to new oral dosage forms for specific patient populations, such as the elderly and patients with dysphagia, for example. Each of these dosage forms will present its own aesthetic challenges that will need to be addressed for the drug products to fully realize the promise of the underlying technology. We hope to contribute to the success of these emerging technologies as well. ♦