Patient-Centric by Design: Formulation Strategies That Improve Pediatric Adherence

To address the challenges of pediatric formulations, specialized technology platforms are often needed to provide ease of administration and improve patient outcomes.

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Pediatric populations represent some of the most diverse patient groups. Individual preferences, physiology, and dosage considerations all complicate drug formulation aimed at pediatric care, and the healthcare field increasingly recognizes the impact that consistent adherence has on a treatment's efficacy. Off-label administration, more common among the youngest and oldest patients, can reduce efficacy and create the potential for medication-related toxicities.

Medication adherence is influenced by many factors, including the method of treatment, healthcare accessibility, socioeconomic status, and a drug's palatability and swallowability. For pediatric patients, adherence is further complicated by a child's ability, or willingness, to accommodate bitterness or challenging textures. Many active pharmaceutical ingredients (APIs) can be masked in common liquid formulations, but numerous bitter APIs benefit from novel taste-masking approaches. The underlying principle is simple: when children can and will take their medications, everyone wins. With regulators emphasizing pediatric co-development from the start, success now depends on engineering compliance into every dose so that therapies work better in real life, not just in the clinic.

What Influences Treatment Adherence in Children

Eating and swallowing are complex behaviors involving more than 30 muscles and nerves, and they differ in young children owing to

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A certified Lean Six Sigma Black Belt, Giuseppe brings over a decade of hands-on experience in applying Lean methodologies to drive process optimization, enhance productivity and improve quality. His work is underpinned by deep expertise in pharmaceutical technologies and industrial processes. Giuseppe holds a bachelor's degree in biology from the University of Milan, Italy.

changes in the pharynx that occur with maturation. In infants, the teeth have not erupted, the hard palate is flatter, and the larynx and hyoid bone sit higher in the neck; with growth, the larynx descends and the pharynx lengthens vertically.[1] These differences have an appreciable impact on how infants and small children swallow, and developers should account for them.

Texture matters as well. Across cultures, mild flavors and smooth textures, as in pudding, apple sauce, and custard, have the broadest acceptability,[2] and oral formulations that mimic these foods tend to exhibit greater adherence. For older children, palatability is arguably the deciding factor: once children are five years old, swallowing begins to mirror that of an adult,[3] so rejection often comes down to individual preference. Given a formulation with the texture and rheology of soft foods, children can swallow boluses well in excess of the one-gram tablet ceiling assumed by industry standards.[4]

Purpose-built pediatric formulations also discourage tampering. Crushing a drug and mixing it with food or beverages has long been common practice among pediatric and geriatric patients, but it can alter release characteristics and increase dissolution and bioavailability, causing too much drug to be absorbed too quickly. Either scenario can be medically serious, particularly for children unable to communicate discomfort.

The Real-World Impact of Getting the Formulation Right

A well-designed pediatric formulation pays dividends beyond the clinic. The most direct benefit is higher adherence: more doses taken means better clinical results. Purpose-built formulations also provide regulatory confidence, meeting strict standards for global markets, while demonstrated acceptability supports reimbursement and formulary inclusion. At the health-system level, they deliver better value, improving outcomes while reducing the overall healthcare burden of treatment failure and dose errors. A pediatric formulation strategy is not simply a technical exercise; it is a commercial and public health strategy.

Taste Masking That Works

Physical barriers remain one of the most efficient taste-masking technologies, and Adare offers commercially feasible platforms, Microcaps® and Optimμm®, for pediatric dosage forms. These advanced technologies eliminate bitter tastes and lead to better acceptance. Microcaps uniformly coat a solid particle or liquid droplet with a rigid, semi-permeable polymer, allowing developers to combine incompatible APIs, customize release profiles, and mask a range of bitter molecules. Optimμm generates uniform microspheres and microcapsules with dose and format flexibility and tailored release kinetics. Both avoid the "sandy" effect sometimes found in powders and ensure ideal control of the dissolution profile.

These multiparticulate approaches also solve a persistent pediatric challenge: dosing across a wide range of body weights. Multiparticulates delivered in stick packs, dry syrups, or orally disintegrating tablets (ODTs) enable precise, weight-based dosing for every child, and orally disintegrating formats designed specifically for children remove the swallowing barrier for many patients. Adare's Parvulet® dosage form goes further, converting a granule or tablet, with a few milliliters of water in a spoon, into a food-like product with the consistency of applesauce in under a minute, with no mixing steps that could introduce error. Taste-masked APIs can be incorporated into the Parvulet composition to combine ease of administration with improved compliance.

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Partnering for Better Pediatric Patient Outcomes

The cost and timelines of developing alternative dosage forms can make companies reluctant to invest. A manufacturing partner with the right experience and facilities can expedite development, particularly for new APIs with varying taste and solubility profiles and introducing formulation expertise into clinical development early broadens acceptance. The goal is not simply to modify a formulation, but to engineer better experiences and better outcomes for every patient.

Adare Pharma Solutions is a global technology-driven contract development and manufacturing organization (CDMO) providing end-to-end integrated services, from product development through commercial manufacturing and packaging, with small molecule expertise focusing on oral dosage forms for the pharmaceutical industry. Adare's specialized technology platforms provide taste masking, customized release, multiparticulate systems, and patient-centric dosing solutions. With a proven history in drug delivery, Adare's facilities in the US and Europe have developed and manufactured more than 65 products sold by customers worldwide including formulations that meet stringent government and public health standards across Asia, Europe, the Americas, and beyond. Its aim is straightforward: to transform challenging molecules into intuitive, patient-centered therapies that improve adherence, clinical success, and quality of life. By partnering with a CDMO like Adare, companies can ensure their drug's formulation fits its target population, meets stringent regulatory standards, and ultimately improves therapy outcomes through better patient adherence.

References

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