

# PEDIATRICS AND NEONATOLOGY

July 25-26, 2019 | Amsterdam, Netherlands

Cirri Marzia, Curr Pediatr Res 2019, Volume 23

## PHARMACEUTICAL TECHNOLOGY: CHALLENGES AND OPPORTUNITIES IN IMPROVING PEDIATRIC DRUG FORMULATIONS

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Pediatric and neonatal therapies represent unique challenges in their management, as most of pediatric drugs are unlicensed or off-label from both the point of view of the pharmacological indication, formulation and administration route. Pediatric therapies impose peculiar dosage forms and administration routes and require continuous dosing adjustments, in relation to children rapid growth. The lack of pharmaceutical products appositely formulated for pediatric use leads to manipulations of dosage forms for adult patients, increasing the risks of adverse drug reactions, which may be more severe or different from those in adults. The large use of extemporaneous preparation obtained starting from products for adults (Tablets, capsules and injectable vials) both in hospital pharmacy or at home leads to poor or uncontrolled dosing accuracy, unknown stability, variable bioavailability, poor compliance for children and care-givers. Another main problem to be solved is the palatability, as recognised by the European Paediatric Formulation Initiative (EuPFI). Several products can result unpleasant in taste and appearance, leading to poor compliance in the pediatric population and thus negatively influencing the relative clinical outcomes. Again, a great problem to consider in the development of pediatric formulations is the stability. Some excipients are essential to improve the chemical stability of the formulation and prevent the microbial growth during storage and use, but their presence can result harmful to children. Special attention must be given to the use of appropriate excipients for children of various ages. The need for developing medicinal products adequately designed for pediatric use has been recently pointed out by the European Medicinal Agency. The biggest challenge in pediatric formulation development is to create flexible and easy to administer dosage forms, able to assure safety, accurate dosing, suitable therapeutic efficacy, palatability and stability. The lecture will be focused on the opportunities offered by the pharmaceutical technology in order to improve pediatric drug formulations.

## BIOGRAPHY

Cirri Marzia has completed her PhD in 2004 at University of Florence, Italy. She is Assistant Professor of Pharmaceutical Technology at University of Florence. She is the author of 66 publications with publication H-index of 31 and 2130 citations. She has been serving as Guest Editor and Referee of reputed journals. She achieved a poster award for her scientific activity regarding pediatric formulations development in 2017. She has carried out teaching staff activities in international countries. She collaborates with several national and international research groups. Her research lines are focused on the improvement of the biopharmaceutical properties of drugs by different strategies.



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