



TITOLO  
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**LEADING THE CHANGE TO SUSTAINABILITY OF QC FOR ATMPs:  
THE EXPERIENCE IN THE ACADEMIC CELL FACTORY AT THE PEDIATRIC HOSPITAL “BAMBINO  
GESU”**

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Riassunto

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The role of the Quality Control ("QC") in a cell factory consists of the execution of all the tests and of the features verification on materials and products so as to guarantee their quality, an essential requirement for their release. Focusing on the principal general topics regarding the role of QC in the production chain of medicinal products (starting and raw materials, manufacturing process, analytical instruments, analytical method validation, environmental monitoring and DP release) we emphasized on the ATMPs QC matters compared to the traditional drug ones. In particular, the definition of quality control tests, specifications, analytical methods and their validation design represents challenging topics that are intensely debated among QC specialists. To face all the ATMP QC challenges, the strategy to be adopted needs to be not limited to the only improvement of the laboratory operations, but has to implement different tools, such as risk analysis, workflow digitalization and multidisciplinary approach to the analytical issues. We summarized how the QC unit of the academic cell factory at the pediatric hospital “Bambino Gesù” managed to better organize the workflow through a combination of multiple skills so as to improve and optimize the QC unit sustainability in the context of the cell factory.

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