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## Cord blood banking. Understanding the critical quality attributes (CQAs) for cell product development and manufacture

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Cord blood banks are a potential source of cellular material for the emerging cell based therapy industry. Umbilical cord blood (UCB) is now a well-recognized source of hematopoietic stem cells and it has a widespread use for transplantation. It has several advantages over bone marrow or peripheral blood, including increased tolerance for Human Leukocyte Antigen mismatches, decreased incidence of graft-versus-host disease (GVHD), and easy availability. These advantages make UCB a desirable cell therapy treatment in the growing need of suitable grafts for patients with hematologic malignancies or underlying bone marrow or metabolic defects. It is also important to note that a significant population of patients, specifically minority groups, lack a suitable HLA-matched bone marrow, or peripheral stem cell donor, consequently UCB is able to fill this gap as an important source of allografts for such groups. Umbilical cord tissue (UCT) banking is also increasing in such facilities as a source of mesenchymal stem cells for future therapeutic use. However, early handling of the placenta and umbilical cord is relatively uncontrolled due to the clinical demands of the birth environment and subsequent transport logistics. It is therefore necessary to develop extraction methods that are robust to real world operating conditions, rather than idealised operation. Also in a recent study performed by our cord blood bank with the help of 50 members of the World Marrow Donor Association (WMDA), a gap in the evaluation of the critical quality attributes (CQAs) of a cord blood unit (CBU) used for transplantation was identified. The results of this study emphasize that a better understanding and communication of UCB parameters and their limitations needs to be established between the Cord Blood Providers Group (CBPG) and the Cord Blood Selectors Group (CBSG). This would allow the CBPG to set parameters that can be translated into standardised testing methods, with proven cross centre reproducibility, and with long standing correlations to engraftment.

### Biography

Andreea Iftimia-Mander is an interdisciplinary scientist with a wide range of expertise in the fields of regenerative medicine and chemical engineering, organic synthesis. She has completed her PhD at the Centre for Biological Engineering, Loughborough University, Loughborough, UK, in the field of Regenerative Medicine. Currently she is the Clinical Processing Manager for Anthony Nolan Cell Therapy Centre in Nottingham, UK.

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