

Certification practices and CAR-T therapy implementation

14.00–16.00

Virtual for participants

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vimeo.com/event/6155916

ABOUT THE WEBINAR

CAR-T therapies create new treatment opportunities, however, they also place specific demands on hospitals, clinicians, industry and regulators. The webinar explores how certification, training, documentation and risk-minimisation requirements affect implementation in practice – and how stakeholders can reduce unnecessary duplication while maintaining patient safety, quality and compliance.

PROGRAMME

TIME	SESSION	SPEAKER / MODERATOR
14.00	Welcome and introduction	Jette Rathe Chief Consultant and Coordinator, MD and PhD, ATMP South Lea Brandt Kristensen JACIE Quality Coordinator, Project Nurse, Aarhus University Hospital
14.05	International perspective on certification practices	Nick van Sinderen JACIE-inspector, Quality Advisor, University Hospital Cologne
14.25	Clinical implementation of CAR-T in the haematology department	Marianne Ifversen Senior Consultant, MD, PhD, Department of Paediatrics and Adolescent Medicine, Rigshospitalet · Denmark
14.40	Danish experience and key challenges	Lasse von Bornemann Fløe Medical Doctor, Clinical Immunology and Haematology, DSKI, Aarhus University Hospital
14.55	Industry Perspective: Implementing CAR-T Cell Therapy - BMS — Manufacturer of CAR-T Cells	Christina Sylvester-Hvid Nordic Medical Affairs, Cell Therapy and Hematology, Bristol Myers Squibb
15.10	EMA PRAC: EU regulatory perspective on risk minimisation and legislation	Karin Erneholm Senior Advisor in Pharmacovigilance, Danish alternate member of PRAC, Danish Medicines Agency
15.20	Danish Medicines Agency – national authority perspective	Nanna Thirstrup Director of Department, Quality Assessment & Clinical Trials, Danish Medicines Agency
15.30	Panel discussion	
15.50	Closure and wrap-up	Moderators