



FACT Quality Boot Camp

Using a Risk Management Framework to Design Effective Validation Plans, Audits, and Corrective and Preventive Actions

prior to the **TANDEM MEETINGS**

February 2, 2026

8:00 AM - 5:00 PM

Grand Ballroom | Hilton Salt Lake City Center
255 South West Temple | Salt Lake City, UT 84101

Hosts



Phillip Johnson, MMedSc(Path)

Director/Scientific Director
Queensland Cord Blood Bank
At The Mater



Kimberly Kasow, DO

Vice-President, Medical and
Quality Services
NMDP

Speakers



Priscilla DaSilva

Senior Manager, TCT
Regulatory/Quality
Management, City of Hope
National Medical Center



Harminder Kaur-Singh, SSGb, CPHQ

Quality Coordinator,
Sarah Cannon Transplant
& Cell Therapy Program at
HCA North Florida



Linh Sellers, CCRP

Clinical Quality Manager,
University of Colorado
Hospital - Cell Therapy Center



Jacklyn Stentz, MBA, BSMT(ASCP), CPHQ

Director Quality
Improvement, HCA
Healthcare Sarah Cannon
Cancer Network

Agenda

Check-in will begin at 7:30 AM. Breakfast is not provided.

Early badge pickup is available Sunday, February 1 from 4:00–5:00 pm
at the Registration Room, across from the Grand Ballroom.

8:00 AM - 8:10 AM (10 MIN)

WELCOME



**8:10 AM - 8:35 AM
(25 MIN)**

QUALITY SYSTEMS INTEGRATIONS



This session focuses on the
interconnectedness of quality
management processes in
cellular therapy programs and
strategies for their integration.

8:35 AM - 9:15 AM (40 MIN)

FOUNDATIONS OF A RISK- BASED FRAMEWORK IN QUALITY MANAGEMENT



This session introduces the core
principles of risk-based thinking
within modern Quality Management
Systems, emphasizing Quality by
Design and proactive risk assessment.

9:15 AM - 9:30 AM (15 MIN)

BREAK

9:30 AM - 10:15 AM (45 MIN)

RISK MANAGEMENT AND OCCURRENCE MANAGEMENT (CAPA)



This session explores how risk management informs occurrence
evaluation and CAPA escalation, prioritization, and level of action.
Participants will apply risk assessment tools to support effective
Occurrence and CAPA decision-making and planning.

10:15 AM - 11:15 AM (60 MIN)

ROUNDTABLE #1 + SHARING DISCUSSION

11:15 AM - 12:00 PM (45 MIN)

LUNCH BREAK



FOUNDATION FOR THE
ACCREDITATION OF
CELLULAR THERAPY

12:00 PM - 12:45 PM (45 MIN)

INTERNAL AUDIT PLANNING AND EXECUTION, A RISK-BASED APPROACH



This session reviews the required elements of audit plans and reports under FACT standards and introduces the principles of risk-based internal auditing. Participants will learn to develop risk-informed audit schedules that prioritize activities based on risk, historical data, and process criticality to support QMS integrity and compliance.

12:45 PM - 1:45 PM (60 MIN)

ROUNDTABLE #2 + SHARING DISCUSSION

**1:45 PM - 2:00 PM (15 MIN)
BREAK**

2:00 PM - 2:45 PM (45 MIN)

MANAGEMENT AND CONTROL OF RISK BY QUALIFICATION AND VALIDATION



This session examines how risk-based thinking guides qualification and validation activities, influencing scope, depth, and frequency. Participants will apply risk assessment tools to design validation plans and protocols that prioritize high-impact systems, processes, and equipment.

2:45 PM - 3:45 PM (60 MIN)

ROUNDTABLE #3 + SHARING DISCUSSION

3:45 PM - 4:25 PM (40 MIN)

INTEGRATION OF RISK ASSESSMENT IN YOUR QUALITY MANAGEMENT PROGRAM FOR CONTINUOUS IMPROVEMENT



This session focuses on integrating risk-based thinking into quality planning and decision-making to support continuous improvement and regulatory compliance. Participants will learn to establish frameworks for monitoring risk trends and evaluating the effectiveness of improvement actions.

4:25 PM - 4:40 PM (15 MIN)

CLOSING WHAT HAVE WE LEARNED?



Facilitators



Therese Dodd, MBA, RN, CPHQ
Senior Consultant,
FACT Consulting Services



Kerri Hill, RN
Director of Quality,
University of Arkansas for
Medical Sciences



**Nicole McEntee, MSN, RN,
OCN, TCTCN**
Program Director Transplant &
Cellular Therapy, Jack & Sheryl
Morris Cancer Center |
RWJBarnabas Health



Cynthia Morris, MSN, RN, CPHQ
Program Manager II-
Transplant Quality,
St. Jude Children's Research
Hospital



**Jennifer Pugliese, MSN, RN,
MEDSURG-BC**
Program Coordinator-
BMT Quality,
SSM Health Cardinal Glennon
Children's Hospital



**Federico Rodriguez,
BSMT, SBB (ASCP)**
Client Services Manager,
FACT Consulting Services



Jean Sanders, MD
Professor Emeritus - Clinical
Research Division, Fred
Hutchinson Cancer Center