



# GCSG 2019 US Conference Workshop Table

Workshop	CE	Workshop Name	Room
<b>Workshop # 1</b> Monday - April 29th 10:15 AM - 11:15 AM	Y	Developments in Expanded Access	Fredericksburg D
	Y	CMC Regulatory Workshop (Filings and how they relate to IP)	Fredericksburg A
	Y	Import and Export of Controlled Substances	Fredericksburg B
	Y	Insource or Outsource cGMP Batch Documentation	Fredericksburg C
	Y	EU Regulation 536/2014 (Clinical Trial Regulation) and the Regulatory Impact on Clinical Supplies.	Uvalde
	Y	Strategies for Using Pooled Supplies	Independence 8
	Y	Annex 13 and Annex VI Requirement Changes OR Changes to EU Regulation 536/2014	Hill Country A
	Y	Artificial Intelligence in Clinical Supplies	Brady
	Y	Vendor Management	Hondo
<b>Workshop # 2</b> Monday - April 29th 11:30 AM - 12:30 PM	Y	Aligning Clinical Supplies Documentation with Trial Master File Expectations	Hill Country A
	Y	Managing Importation Requirements for Your Products	Fredericksburg G
	Y	Temperature Data at the Clinical Site - The Missing Piece of the Puzzle	Hondo
	Y	How to Partner with Your Clinical Sites, a Shared Perspective from a Site Pharmacist and CMO	Independence 6
	Y	Enrollment Accuracy & Forecasting	Independence 8
	Y	Autologous Therapy Supply Chain Strategies	Independence 7
	Y	Challenges of Developing a Clinical Supply Chain in Asia Pac	Fredericksburg D
	Y	Best Practices for Adaptive Trials	Brady
	Y	BREXIT's Impact on Distribution	Hill Country D
<b>Workshop # 3</b> Tuesday - April 30th 10:00 AM - 11:00 AM	Y	Quality Agreements	Fredericksburg F
	Y	Social Media and Its Influence on Clinical Trial Recruitment	Fredericksburg B
	Y	Insource or Outsource cGMP Batch Documentation	Fredericksburg A
	Y	Maintaining a Patient-First Perspective in Your Clinical Supply Chain	Fredericksburg E
	Y	Best in Class Temperature Controlled Distribution	Hill Country B
	Y	The Future of Automated Systems for Clinical Supplies	Hill Country C
	Y	Planning Returns & Reconciliation in a Global Trial Following Regulations in Latin America	Fredericksburg G
	Y	Annex 13 and Annex VI Requirement Changes OR Changes to EU Regulation 536/2014	Fredericksburg D
	Y	Ancillary supplies - Partnering with CROs	Hondo
<b>Workshop # 4</b> Tuesday - April 30th 11:15 AM - 12:15 PM	Y	CMC Regulatory Workshop (Filings and how they relate to IP)	Fredericksburg C
	Y	Direct to Patient	Fredericksburg D
	Y	Enrollment Accuracy & Forecasting	Fredericksburg F
	Y	EU Regulation 536/2014 (Clinical Trial Regulation) and the Regulatory Impact on Clinical Supplies.	Hill Country C
	Y	Comparator Sourcing Strategies	Hill Country B
	Y	Vendor Management	Hill Country A
<b>Workshop # 5</b> Tuesday - April 30th 1:45 PM - 2:45 PM	Y	Managing Importation Requirements for Your Products	Fredericksburg E
	Y	Import and Export of Controlled Substances	Fredericksburg C
	Y	How to Partner with Your Clinical Sites, a Shared Perspective from a Site Pharmacist and CMO	Hondo
	Y	Strategies for Using Pooled Supplies	Uvalde
	Y	Autologous Therapy Supply Chain Strategies	Fredericksburg F
	Y	Artificial Intelligence in Clinical Supplies	Hill Country D
	Y	Challenges of Developing a Clinical Supply Chain in Asia Pac	Hill Country C
	Y	Best Practices for Adaptive Trials	Fredericksburg G
<b>Workshop # 6</b> Wednesday - May 1st 10:30 AM - 11:30 AM	Y	Quality Agreements	Fredericksburg G
	Y	Social Media and Its Influence on Clinical Trial Recruitment	Fredericksburg E
	Y	Temperature Data at the Clinical Site - The Missing Piece of the Puzzle	Hondo
	Y	Best in Class Temperature Controlled Distribution	Uvalde
	Y	The Future of Automated Systems for Clinical Supplies	Hill Country D
	Y	Annex 13 and Annex VI Requirement Changes OR Changes to EU Regulation 536/2014	Hill Country C
	Y	Challenges of Developing a Clinical Supply Chain in Asia Pac	Hill Country A
<b>Workshop # 7</b> Wednesday - May 1st 1:00 PM - 2:00 PM	Y	Cell Gene Therapy Supply Chain	Hill Country B
	Y	Direct to Patient	Fredericksburg D
	Y	Maintaining a Patient-First Perspective in Your Clinical Supply Chain	Fredericksburg E
	Y	Enrollment Accuracy & Forecasting	Fredericksburg A
	Y	EU Regulation 536/2014 (Clinical Trial Regulation) and the Regulatory Impact on Clinical Supplies.	Hill Country D
	Y	Planning Returns & Reconciliation in a Global Trial Following Regulations in Latin America	Fredericksburg F
	Y	Comparator Sourcing Strategies	Brady
Y	Ancillary supplies - Partnering with CROs	Fredericksburg B	

## Accreditation Statement



In support of improving patient care, this activity has been planned and implemented by the University of Wisconsin–Madison Interprofessional Continuing Education Partnership (ICEP) and the Global Clinical Supply Group (GCSG). The University of Wisconsin–Madison ICEP is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

## Credit Designation Statements

### **American Nurses Credentialing Center (ANCC) & Iowa Board of Nursing**

The University of Wisconsin–Madison ICEP designates this live activity for a maximum of 14 ANCC and Iowa contact hours.

The University of Wisconsin-Madison School of Nursing is Iowa Board of Nursing provider 350. A copy of the evaluation(s) may be sent to the Iowa Board of Nursing, 400 SW 8th St., Suite B, Des Moines, IA 50309.

\*Only sessions marked with CNE in the Agendas are approved for ANNC and Iowa Board of Nursing contact hours.

### **Accreditation Council for Pharmacy Education (ACPE)**

The University of Wisconsin–Madison ICEP designates this live activity for a maximum of 14 hours (1.40 CEUs) of CPE credit. Credit can be earned by documented attendance and by successfully completing the assessment and evaluation. Credit will be provided to NABP CPE Monitor within 60 days after the activity completion.

Specific information regarding the Universal Activity number(s), and learning objectives will be provided in activity materials.

\*Only sessions marked with CPE in the Agendas are approved for CPE credit .

Note: The deadline for claiming pharmacy CE credit is June 9, 2019.  
No late CPE requests will be accepted.