



**An Accreditation With Real Benefit:  
Why CCE Enhances Quality and  
Credibility**

**Joseph P. Navarra, RPh, FACA, FAPC**  
**Owner, Town Total Compounding Center**

1

**What is the Coalition for  
Compounding Excellence (CCE)?**

**The short answer:**  
**A fresh, collaborative, affordable  
pathway  
to compliance and quality.**



2

## What's “Fresh” About It?

1. Broad scope
2. Risk-based versus checklist-approach to auditing
3. Collaborative approach
4. Unprecedented auditor investment
5. On-going monitoring and support
6. Alignment with greater world of auditing



3

## 1. Broad Scope

- Prepare clients for whomever might walk in the door:
  - USP
  - OBRA 90
  - GDP – Good Documentation Practices
  - HIPAA
  - DEA
  - FDA
  - State boards of pharmacy
  - Nonresident licensure inspections



4

## 2. Risk-Based Versus Checklist-Approach to Auditing

- How does CCE define “risk”?
- Based on FDA’s ICH Q9(R1) definition:
  - Risk = Severity X Probability X Detectability
- Scope of risk:
  - Patient harm
  - Worker harm
  - Financial harm
    - Litigation
    - Regulatory
    - Operational efficiency

**More on  
this later!**



5

## 3. Collaborative Approach

- Premium placed on providing suggestions and information, not just findings
- Deficiency encountered? Auditor immediately clicks into “solution mode” with the client
- Many pharmacies might be surprised at the number of initial “findings”
- CCE is committed to help you create, complete effective plans of correction



6

### 3. Collaborative Approach

"[CCE's] competitors either critique and "leave the building," providing no insight into how to resolve deficiencies, or have such a high "pass rate" that the value of accreditation to stakeholders, providers, and the public is diminished."

- *Danny Barnes PharmD BCSCP, Chief Pharmacy Officer/President, Triangle Compounding Pharmacy, Cary NC*



7

### 4. Unprecedented Auditor Investment

- No other 503A accreditor invests the number of auditor hours that CCE does:

Service	Remote Auditor Hours	On-Site Auditor Hours
Sterile & Nonsterile	8	10
Sterile only	6	8
Nonsterile only	4	7



8

## 5. On-Going Monitoring and Support

“Many pharmacies got serious about quality – about three months before they were due for their next survey.”

- Rad Dillon, former PCAB surveyor

- CCE requires the submission of a small number of documents to maintain accreditation
- If this is seen as onerous, the client has far bigger problems!
- Ongoing mini-self-audits
- Ongoing presentations on key topics
- While CCE refers clients desiring true consultative services to a small list of other entities, we’re always there to offer answers and advice



9

## 6. Alignment with greater world of auditing

- SOPs structured to comply with ISO 19011 - Guidelines for auditing management systems
- Medium Term Goal 1: “Registration” by ISO/IEC 17020 - Inspection Body Accreditation Program
- Medium Term Goal 2: Accreditation by ISQua EEA - Guidelines and Principles for the Development of Health and Social Care Standards



10

## What's “Affordable” About it?

- Low overhead → low cost
  - Auditors only engaged when deposit check received
- Top-heavy, highly-compensated layers of management avoided

Service	Remote & On-Site:		Remote Auditor Hours	On-Site Auditor Hours	Remote Only:	
	APC Membership:				APC Membership:	
	Individual	PFM			Individual	PFM
<b>Sterile &amp; Nonsterile</b>	\$ 12,000	\$ 8,000	8	10	\$ 4,600	\$ 3,000
<b>Sterile only</b>	\$ 11,000	\$ 7,500	6	8	\$ 3,900	\$ 2,600
<b>Nonsterile only</b>	\$ 10,500	\$ 7,000	4	7	\$ 3,200	\$ 2,100



11

## But CCE Retains Some “Old” Traits

- A return to auditors with deep experience and expertise
- A two-phase process:
  - Preliminary office review of most documents
  - On-site audit focused on observation, follow-up, interactions
  - Multiple eyes on your processes and paperwork



12

## What About Nonresident License Inspections?

- **Hybrid approach:**
  - On-site inspection performed by a third party
  - Client shares report with CCE
  - CCE requests modest amount of additional documentation
  - CCE conducts remote audiovisual, risk-based audit



13

## Risk-Based Versus Checklist-Approach to Auditing

- **Traditional checklist-inspecting:**

Strengths	Weaknesses
Ensures baseline compliance	High-risk issues not highlighted: broken taillight syndrome
Low auditor qualifications needed	Lists often too short or too long
Clear pass / fail results	Poor at identifying root causes



14

## Risk-Based Versus Checklist- Approach to Auditing

- Risk-based auditing:

Strengths	Weaknesses
Identifies high-risk issues	Can appear subjective
Auditors can be more interactive	Requires skilled auditors
Aligns with FDA, ISO language	Can take more time

15

## Checklist Approach: All Findings Are Created Equal

Topic	Observation
Compounding facilities meet all USP requirements re construction and maintenance	Seam in anteroom floor near entrance observed to be not fully caulked.
Hand hygiene and garbing performed appropriately	Technician preparing for nonsterile compounding was observed to wash hands less than 30 seconds.
Quality control and assurance steps present for all critical processes	Upon interview PIC stated that she does not have new or revised MFRs checked by a coworker.
Quality management reports are present, include all required elements, present trended data as appropriate, and are reviewed by management	Interview revealed that the pharmacy has never created quality management reports.

16

## Risk-Based Approach: Not All Findings Are Created Equal

Topic	Observation	S (1-5)	P (1-5)	D (1-5)	RPN	Risk Level
Compounding facilities meet all USP requirements re construction and maintenance	Seam in anteroom floor near entrance observed to be not fully caulked.	1	5	1	5	Low
Hand hygiene and garbing performed appropriately	Technician preparing for nonsterile compounding was observed to wash hands less than 30 seconds.	1	5	1	5	Low
Quality control and assurance steps present for all critical processes	Upon interview PIC stated that she does not have new or revised MFRs checked by a coworker.	4	5	5	100	Critical
Quality management reports are present, include all required elements, present trended data as appropriate, and are reviewed by management	Interview revealed that the pharmacy has never created quality management reports.	5	5	5	125	Critical

17

## Pulling the Thread

- "Pulling the thread" - the act of investigating a small, initial clue, query, or problem that leads to uncovering a much larger, often hidden, and complex situation.
- Goal: **help** the client, not look for "broken tail lights"

18

## Pulling the Thread: Case Study

- **Criterion 7.2** - Complaints / incidents / errors / near misses are documented and addressed.
- **Finding:** That the Complaint Log has only one entry for the last 24 months indicates an inadequate reporting process for such events.

## Pulling the Thread: Case Study

### Checklist-Based Next Step:

- Mark as “compliant” and move on:
  - You can’t create a finding called “Client isn’t reporting enough complaints!”
  - You’ve got a zillion more boxes to check!

## Pulling the Thread: Case Study

### Risk-Based Next Steps:

- Auditor walks to front end of pharmacy for ten minutes, hears several incoming calls that sound like patients reporting problems.
- Auditor verifies with one of these clerks that the patient in fact was worried that she'd not received her medication ordered last week.



21

## Pulling the Thread: Case Study

- **Auditor:** Do you think that would constitute a “complaint”?
- **Clerk:** “Maybe, but I don’t know where a copy of our complaint form is – and we just don’t have time fill them out anyway: they’re way too long!”



22

## Prompts Additional Auditor Observations

- **Under-reporting of complaints:** One complaint in 24 months is not credible given observed patient problem calls, indicating failures to capture and log complaints, incidents, and near-misses.
- **Poor definition / training:** Front-end staff do not clearly understand what a “complaint” is, nor their responsibility to document it (“don’t know where a copy of that complaint form is,” “don’t have time”).
- **Nonfunctional procedures:** Complaint forms are hard to find and too burdensome, so the written process is not effectively implemented in daily operations.



23

## Prompts Additional Auditor Observations

- **Weak CAPA and risk management:** If complaints are not recorded, investigations, trend analysis, and CAPAs are not triggered, undermining Criterion 7.2's requirement to document and address such events.
- **Inadequate QA / management oversight:** Leadership is not reconciling expected complaint volume (e.g., call activity) with the complaint log, ***suggesting a deficient quality management system and management review process.***



24

## Pulling the Thread

- Nit picking? Better CCE than others who might walk in your door!
- Findings and subsequent thread-pulling often lead to similar root causes.
- Clients can then address root causes, not apply bandages



25

## Risk-Based Versus Checklist- Approach to Auditing

- **Goldilocks solution:**
  - Relatively short checklists based on common high-risk areas
  - Auditor discretion as to where to pull threads



26

## Conclusions

- Broad scope
- Risk-based versus checklist-approach to auditing
- Collaborative approach
- Unprecedented auditor investment
- On-going monitoring and support
- Low overhead → low cost



27

## Learn More

- CEE website:
  - <https://www.cce-team.com>
- Q9(R1) Quality Risk Management: Guidance for Industry:
  - <https://www.fda.gov/media/167721/download>
- ISO/IEC 17020:
  - <https://www.iso.org/standard/52994.html>
- ISQuaEEA:
  - <https://ieea.ch>



28

## Contact Information

Joseph P. Navarra, RPh, FACA, FAPC  
Owner  
Town Total Compounding Center

[joseph.navarra@towntotalcompound.com](mailto:joseph.navarra@towntotalcompound.com)

516-249-7436



29



30