

## Course Materials

The supplies you will need are:

- PowerPoint: **Guide to Internal Auditing** (included).
- PowerPoint: **Requirements of ISO 13485** (included).
  - A complete version with Speaker Notes is in this Trainer's Guide
- PowerPoint: **Steps of Internal Audit** (included).
  - A complete version with Speaker Notes is in this Trainer's Guide
- Student Manual (included).
  - Ø Print one copy for **each student**
  - Ø You may wish to have extra copies of the CPAR form
  - Ø It includes reduced versions of all the PowerPoints.
- Sticky Bubble Gum Company Documents and Records (included).

Qty	Sticky Bubble Gum Documents and Records	# of Pages
1	Quality Manual .....	10
1	Internal Audit Master Schedule .....	1
1	P-4.2-009 Control of Documents Procedure.....	2
1	Master Document List .....	1
1	P-5.0-002 Management Responsibility Procedure.....	3
1	SBG Organizational Chart .....	1
2	Management Review Minutes.....	2
1	P-7.2-005 Customer Related Processes Procedure.....	2
4	Quotes with Client PO's.....	8
1	P-7.4-004 Purchasing Procedure.....	2
1	F-7.4-005 Approved Vendor List Form.....	1
7	SBG PO's to SBG Vendors .....	7
3	F-7.4-003 Subcontractor Problem Log Form.....	3
1	Product Flow Chart.....	1
1	750-W-30 Bulk Gum Batching Work Instructions.....	2
1	750-W-140 Texturizing Work Instructions.....	2
1	P-8.3-003 Control of Nonconforming Product Procedure.....	1
1	P-8.5-001 Corrective Action Procedure.....	2
1	F-8.5-002 Corrective Action Log Form.....	1
11	F-8.5-001 Corrective Action Request (CAR) Form.....	11
2	F-852-001-A Corrective/Preventive Action Request (CPAR) Form...	4

Ø Print one copy for **each team** of two or three students.

- The ISO 13485 Standard (**NOT Included\***)
  - Ø One copy for every 2-3 students.
  - Ø Standards are available electronically from <http://www.13485store.com/Buy-Standards.aspx>

\* The ISO 13485 Standard is a copyrighted document and we are unable to include it.