

Global Harmonization Meeting Facilitator Notes

Work Session Facilitators

Working Session	Facilitator (Common)	Facilitators (Breakout)	Recorder
Introduction	KathleenK JohnB SoniaW		
Manufacturing-Upstream	JohnB.	Niall SoniaW.	Community College Attendee
Manufacturing-Downstream		Jose JohnB.	Community College Attendee
Quality Control-Microbiology	JohnB.	Valerie SoniaW	Community College Attendee
Quality Control-Chemistry		KathleenK JohnB	Community College Attendee
Process Development		KathleenK. Sonia W.	Community College Attendee
Validation		TBD John B.	Community College Attendee

NOTES:

- **Facilitators:** SoniaW or JohnB will plan on being in one of the two breakout sessions. In addition, we have asked one other person from the planning group to help facilitate. As envisioned:
 - One person can guide and monitor discussion as a subject matter expert, ensuring focus is on tasks and content relevant to the position across the industry as a whole.
 - One person can ensure process keeps moving so that the whole process is completed in the allotted time.
 This is just preliminary thinking, and subject to change based on general input from facilitators.
- **Recorders:** As breakout groups convene, facilitators should recruit a community college attendee to act as a recorder, capturing the necessary information in the Excel spreadsheet.

Global Harmonization Meeting Facilitator Notes-2

Operational Notes (Continued)

1. INTRODUCTION (Defining Meeting Parameters)

Introduce, discuss, and obtain consensus on:

- The nature of the product and the needs it will serve.
- Specific Jobs Analyzed
- Level of Experience Targeted (six months after hire)
- Meeting Process

Tools Provided Include:

- Key Functions & Tasks Handout (compiled from existing standards)
- Existing Standards
- EXCEL WORKSHEET (blank, pre-numbered framework)

2. DETERMINE KEY FUNCTIONS

Discuss and obtain consensus on the key functions that comprise each job in question.

- **Definition:** Key Functions (also called critical job functions or key activities) are broad groupings of the major responsibilities that make up a given job. They should be broad enough in scope that they themselves are comprised of between 4 and 12 types of tasks.

Tools Provided Include:

- Key Functions & Tasks Handout (compiled from existing standards)
- Existing Standards
- EXCEL WORKSHEET (w/ key functions from Step 2 above)

3. DETERMINE TASKS

Discuss and obtain consensus on the individual tasks that comprise each key function for each job in question.

- **Definition of "Task:"** Tasks are the individual duties and activities required to perform a given key function. Together, a group of tasks should present a representative description of a given Key Function.

Tools Provided Include:

- Knowledge & Skill Master Handout (compiled from existing standards)
- Existing Standards
- EXCEL WORKSHEET (with tasks/functions from prior steps)

4. DETERMINE COMPETENCIES (Knowledge and Skill)

Discuss and obtain consensus on the knowledge and skill requisite to perform each task.

- **Definition of "Knowledge:"** Knowledge includes an organized body of factual or procedural information.
- **Definition of "Skill:"** Proficiency in manual, verbal, or mental manipulation of data, people, or objects.

5. Reconvene and Review

Reconvene from breakout groups (if necessary), review findings, and identify gaps / known issues.

NOTES:

- Key need is to make sure everyone is on the same page and envisioning the same job/position/employee.
- High-level job descriptions are in a number of publications for reference
- Topics to address include:
 - Representative job title?
 - Alternate job titles?
 - Education Required
 - Prior Industry experience required?

NOTES:

- We'll start this as a larger group for related jobs as many "key functions" may be common between up and downstream manufacturing and QC chem. and micro.
- Split into subgroups if necessary to complete (we may not need to if common "key functions" are identified for related jobs)
- Think broad enough such that we avoid having a "key function" with only 1 task in it...
- Key Function/Task Handout was compiled from Sonia and other's Standards, and is not necessarily complete, nor is it necessarily void of all redundancy...This is our starting material
- Utilize EXCEL spreadsheet (see next page in this document) for capturing final data, whiteboards may work better for discussion

NOTES:

- Tasks should be broad enough such that we have no more than 12 tasks per key function.
- Key Function/Task Handout was compiled from Sonia and other's Standards, and is not necessarily complete, nor is it necessarily void of all redundancy...This is our starting material
- Utilize EXCEL spreadsheet (see next page in this document) for capturing final data, whiteboards may work better for discussion

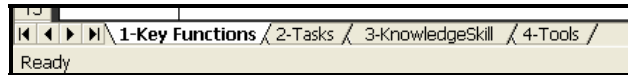
NOTES:

- Knowledge and Skill master picklist was compiled from all skill standards, and based on organizational framework utilized in NCBC's The Model Employee
- The master list does not organize or distinguish between knowledge or skill items unless originally phrased as one or the other in the source document. Designating a given item requires hands-on experience will indicate it needs to be a skill
- This list does not contain all of the detail in some of the source documents so that list is manageable (SOP-like knowledge/skill from Sonia's and ACS's catalog of knowledge on a topic for examples)...this detail can be added after the meeting when necessary
- Allow/encourage adding/tweaking/elaboration on individual knowledge and skill items (detail is always good, what exactly does someone need to know about topicX)
- Utilize EXCEL spreadsheet (see next page in this document) for capturing final data, whiteboards may work better for discussion

Global Harmonization Meeting Facilitator Notes-3

Using the Excel Spreadsheet

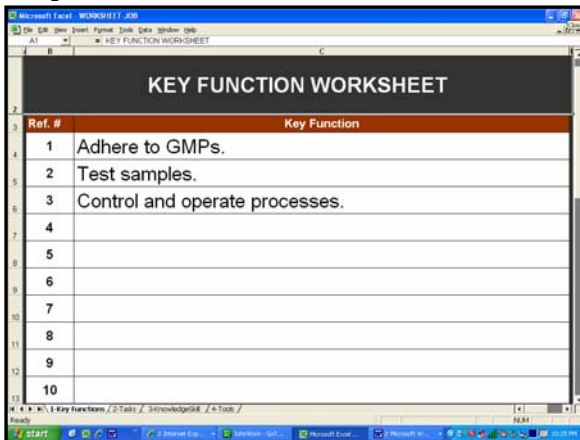
General Introduction. The Excel spreadsheets have been designed to facilitate the data collection process for this meeting. The Excel file consists of 4 separate spreadsheets. Navigate between the spreadsheets by utilizing the tabs at the lower left corner of the screen:



Naming. We will develop one Excel file for each job analyzed. Please name files appropriately for easy identification.

Use Copy/Paste. With the exception of the knowledge and skill master list, this worksheet is blank. Utilize the available draft documents and source standards to copy and paste text if appropriate.

1-Key Functions: Determine Key Functions

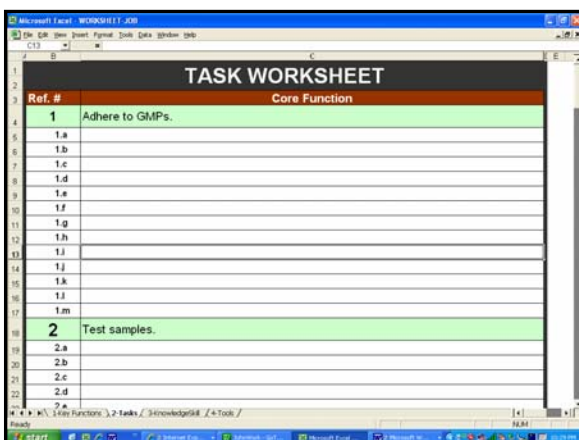
A screenshot of the 'KEY FUNCTION WORKSHEET' in Excel. The worksheet has a title bar 'KEY FUNCTION WORKSHEET' and a table with two columns: 'Ref. #' and 'Key Function'. The table contains the following data:

Ref. #	Key Function
1	Adhere to GMPs.
2	Test samples.
3	Control and operate processes.
4	
5	
6	
7	
8	
9	
10	

This tab/worksheet is pretty straightforward. As consensus is reached, record key functions in the appropriate place.

Note that data entered on this tab will carry throughout the other tabs to minimize re-entering the same data.

2-Tasks: Determine Tasks

A screenshot of the 'TASK WORKSHEET' in Excel. The worksheet has a title bar 'TASK WORKSHEET' and a table with two columns: 'Ref. #' and 'Core Function'. The table contains the following data:

Ref. #	Core Function
1	Adhere to GMPs.
1.a	
1.b	
1.c	
1.d	
1.e	
1.f	
1.g	
1.h	
1.i	
1.j	
1.k	
1.l	
1.m	
2	Test samples.
2.a	
2.b	
2.c	
2.d	

Similar to the previous tab, this tab is also pretty straightforward. Enter tasks as consensus is reached.

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3-KnowledgeSkill: Determine Competencies

Competencies Master List Knowledge and/or Skill Statements		Key Function 3: Control and operate processes.												
		Task 3.A	Task 3.B	Task 3.C	Task 3.D	Task 3.E	Task 3.F	Task 3.H	Task 3.I	Task 3.J	Task 3.K	Task 3.L	Task 3.M	
Writing validation protocols for analytical methods											2	2	2	2
Principles governing choice of key process parameters to validate, and setting operational specifications														
Knowledge of GAMP and software validation practices														
General Plant Operations														
Plant Utility Systems														
Water-types typically used in pharmaceutical operations DI, WFI, USP		2	2	2	2	2	2	2	2	2	2	2	2	2
Chilled water		1	1	1	1	1	1	1	1	1	1	1	1	1
CIP solutions		1	1	1	1	1	1	1	1	1	1	1	1	1
Steam and clean steam; SIP systems		1	1	1	1	1	1	1	1	1	1	1	1	1
HVAC (particle counts, classifications)		2	2	2	2	2	2	2	2	2	2	2	2	2
Instrument and process air		1	1	1	1	1	1	1	1	1	1	1	1	1
Other gases		1	1	1	1	1	1	1	1	1	1	1	1	1
Electrical systems/power distribution		1	1	1	1	1	1	1	1	1	1	1	1	1
Waste collection and processing systems		1	1	1	1	1	1	1	1	1	1	1	1	1
Process Equipment														
Use data logging devices		2H	2H	2H										
Working knowledge of common types of pumps, piping, tanks, valves, agitators, heat exchangers, and solids handling equipment used in pharmaceutical/bioprocess manufacturing		3H	3H	3H	3H	3H	3H	3H	3H	3H	3H	3H	3H	3H
Principles of piping and pump sizing		2H	2H	2H	2H	2H	2H	2H	2H	2H	2	2	2	2
Characteristics of materials used in pumps, piping, tanks, and valves		1	1	1	1	1	1	1	1	1	1	1	1	1

Knowledge and skill master list. Scroll up and down to view the entire list.

Key Function and numerical task references. Scroll left and right to move between key functions.

The first two columns have a legend built into the cell for quick reference. Rolling over the cell will activate. (more details below)

Use this column to designate a rating of knowledge and skill that is required for all functions and tasks for the particular job in question.

Use these columns to rate the knowledge and skill for a particular task/function.

Editing the Knowledge and Skill Master List

As mentioned previously, participants may suggest additions, deletions, and changes to this master list.

Weighting Competencies

Enter level of mastery and whether or not hands-on experience is necessary. If hands-on experience is required, please indicate with an "H" beside the number.	
1 or 1H	<i>Basic</i> introduction and overview of the subject matter and important terminology.
2 or 2H	<i>Intermediate</i> treatment of the subject matter with more exposure to the science and scientific understanding such to support basic troubleshooting.
3 or 3H	<i>Advanced</i> treatment of the subject, with scientific understanding necessary to support high-level analysis and problem-solving.

Utilize the legend at left to indicate both the level of knowledge required to perform a given task and whether hands-on experience is required.

Leave cells blank if that particular competency is not necessary for the given task.