Final Summation Report Accompanying Deliverables

under Award # HHSF223201310208C

International Food Protection Training Institute (IFPTI)

Regulatory Affairs Professionals Society (RAPS)

This report functions as a summary for Year 1 of the project aimed at developing a global curriculum framework for basic level regulators of food (including feed) and medical products (pharmaceuticals and medical devices), with a specific focus on regulators working in low- to middle-income countries (LMIC).

In 2012, the Institute of Medicine (IOM) released a report, Ensuring Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad. In the report, the IOM committee presented the core elements of a food and medical product regulatory system, which include international cooperation and harmonization of standards; using science and risk as the basis for developing policy; collecting evidence when legal breaches occur; integrating staff development and training; and integrating emergency response procedures. The IOM also identified minimal elements of a regulatory system, which include having an established rule-making process; the ability to work within and across agencies during an emergency; a system for stakeholder public comment; and the means to enforce the system's regulations. To that end, according to the IOM, regulators should have access to surveillance data, should understand the source of the data, should be able to identify data gaps, and should have the ability to utilize crisis early warning systems to make the most of limited surveillance data.

The IOM report also identified "regulatory workforce" as one of nine (9) critical issues faced by regulators around the world, and indicated that the recruitment, development, and

retention of such a staff are especially problematic not only among LMICs, but also among developed economies.

Following release of the IOM report, the U.S. Food and Drug Administration (FDA) requested the IOM convene a multi-stakeholder group to develop strategies and approaches for building a global competent regulatory workforce and developing global curricula to educate and train regulators. The group included representatives from the FDA, the World Health Organization (WHO), the Pan American Health Organization (PAHO), organizations involved with food and medical product regulation, and donor organizations. The stakeholder group identified the following key concepts:

- the regulatory profession needs defined basic competencies[1];
- training curricula should be developed based on the competencies;
- the competencies should apply universally;
- the training curricula should also contain additional elective modules;
- the training curricula must be developed by multiple stakeholders; and
- the curricula should become widely available, and become the domain of at least one international organization with expertise on LMIC regions.

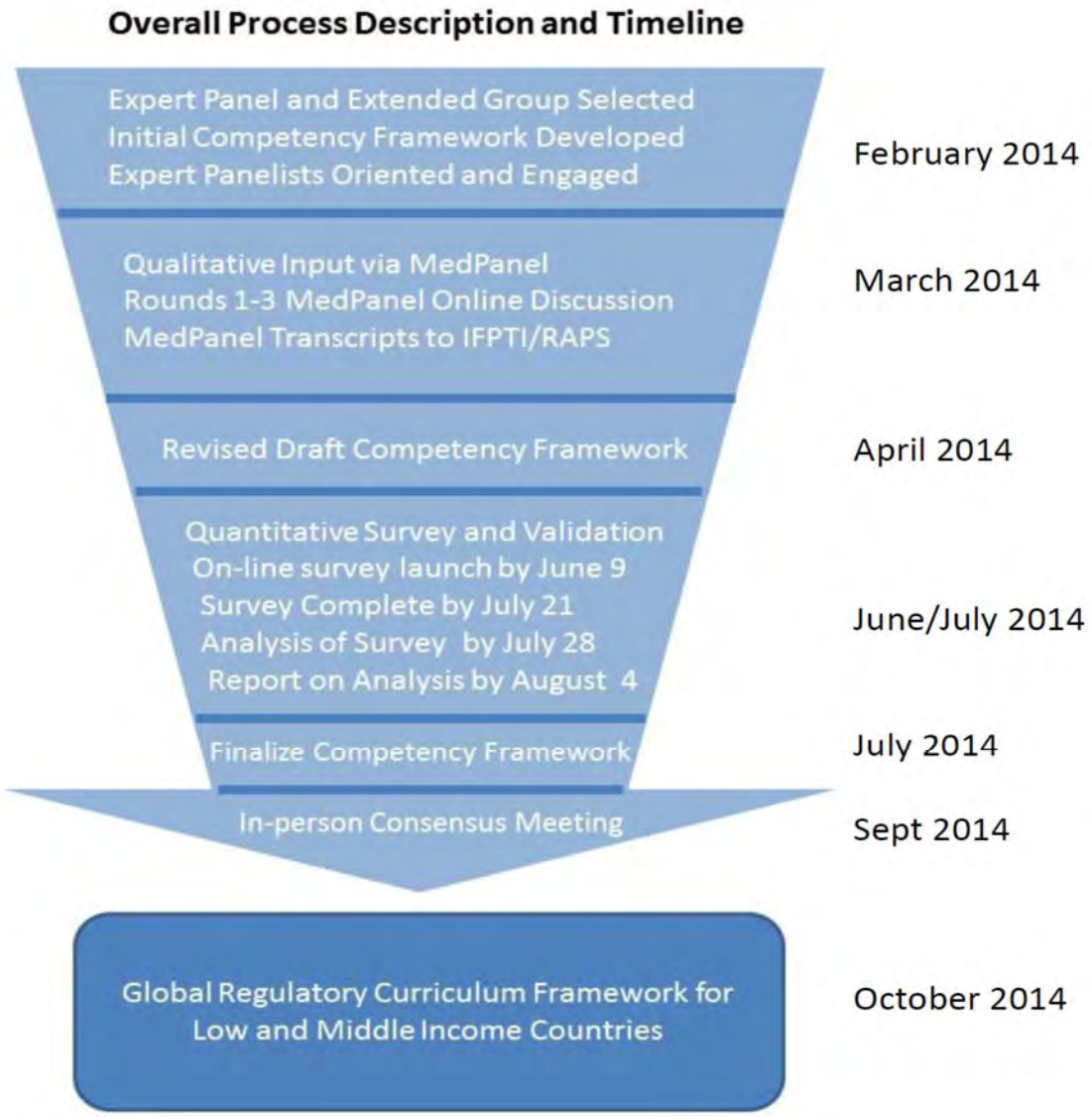
Based on the group's recommendations, it was determined that the current project should have the following three (3) major outcomes:

[1] Competency statements reflect the ability to apply or use knowledge, skills, and abilities to successfully perform "critical work functions" or tasks in a defined work setting. Competencies often serve as the basis for skill standards that specify the level of knowledge, skills, and abilities required for success in the workplace. Evaluation of a person's abilities using a set of established competency statements helps identify competency gaps and training or experiences to address those gaps.

1. Define the basic core competencies of a regulatory professional working with food and/or medical products, particularly regulatory professionals working in LMIC regions.
2. Develop a curriculum framework that will form the foundation upon which a curriculum will be built for educating and training the regulatory workforce in LMIC regions.
3. Develop a competency gap assessment tool to be used by organizations and governments to determine their specific needs and approaches for regulatory workforce training, education, and development.

Figure 1. Project Description and Timeline

Towards the end of calendar year 2013, the project and project timeline were mapped out as shown in Figure 1 on the following page.



Expert Panel and Extended Advisory Group

During the initial weeks of 2014, IFPTI and RAPS accepted nominations for 1) an Expert Panel (12 members on the food side, 12 on the medical products side), and 2) a larger, extended advisory group consisting of approximately 50 individuals with expertise in food

regulation, medical product regulation, or both. Together, IFPTI and RAPS received approximately 75 nominations. Confirmation emails, along with resources related to the overall project, were sent to all selected expert members during the first week of February, 2014. Table 1 on the following pages illustrates the representation of the panels.

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Table 1. Expert Panel and Extended Advisory Group Representation

Industry	Academia	International / National Organizations	Governmental Agencies/Departments
Janssen	University of Copenhagen	WHO	Ministry of Agriculture (Chile)
Abbott Nutrition	University of Zambia	UNIDO	Health Canada
Johnson & Johnson	Nanyang Polytechnic University (Singapore)	Inter-American Institute for Cooperation on Agriculture (IICA)	Center for Agribusiness and Rural Development (Armenia)
VLM Foods	Michigan State University	US AID	Ministry of Agriculture and Livestock (Zambia)
Merck	Iowa State University	Pan-American Health Organization (PAHO)	Health Sciences Authority (Singapore)
Philips Healthcare	University of Florida	UN FAO	Ministry of Health (Peru)
Wipro Technologies	Cornell University	National Codex Commission	Taiwan FDA
Brandwood Biomedical		APEC Food Safety Cooperation Forum	Pharmacy and Poisons Board (Kenya)
Roche Molecular Systems		International Life Sciences Institute (ILSI)	
Probiomed		New Partnership for Africa's Development	
GE Healthcare (Mexico)		National Environmental Health Association (NEHA)	
Proctor & Gamble		Institute of Food Technologists (IFT)	
Bausch & Lomb (Japan)			

Elekta Medical Systems			
Bard Medical			
Cytos Biotechnology			

Qualitative Input Via MedPanel

After formation of the Expert Panel and extended advisory group, IFPTI and RAPS drafted a "straw man" set of sixty two (62) competencies. IFPTI engaged MedPanel, a market research outfit that works primarily in the life science industry, to conduct a series of three (3) rounds of online survey questions with the Expert Panelists using the outfit's online survey platform. Accompanying the instructions for taking the survey was a discussion guide, explaining the purpose of the surveys, along with instructions regarding use of the online platform. Each round of questioning asked the Expert Panelists to rate the utility of each competency, and to offer any comments or feedback.

The first survey round took place during the first week of March, 2014, and utilized the set of sixty two (62) competencies. The draft competencies were initially divided into 4 categories, as defined below.

1) Core Professional Competencies: competencies related to the overall professional characteristics and behaviors of the individual, and that apply across the medical product and food safety sectors;
2) General Regulatory Competencies: competencies that are specific to the regulatory profession, yet apply across the medical product and food safety sectors;
3) Food Technical Competencies: competencies that are specific to the food regulatory profession; and
4) Medical Devices / Pharmaceutical Technical Competencies: competencies that are specific to professionals who regulate medical products.

Revised Draft Competencies

Based on survey results and analysis, the set of competencies was modified: some competencies were eliminated while others were combined or edited. This process was repeated two more times during the month of March, 2014. After the three rounds of surveys, the set of

competencies was slightly reduced. A final transcript of all three rounds of surveys was prepared by MedPanel and sent to IFPTI and RAPS.

Quantitative Survey and Validation

With a revised set of competencies now in hand, the quantitative phase of the project began, during which feedback was sought from a much broader audience of professionals working with food safety and/or medical products. IFPTI and RAPS created a survey on Survey Monkey, asking respondents to rank the importance of each of the competencies contained in the revised draft. Invitations to complete the survey were sent out to the extended advisory group members, the original Expert Panelists, and to the entire IFPTI and RAPS contact databases. Included in the invitation was a request to share the survey link with colleagues and contacts. The goal was to have as many people as possible complete the survey. The survey was launched during the first week of June, 2014, and remained active and open through the end of July, 2014 (approximately two months).

Finalize Competency Framework

Overall, more than three hundred fifty individuals responded to the survey, with approximately 1/3 of the respondents representing food, and approximately 2/3 representing medical products. About half of the survey respondents represented the private sector, while the other half represented the public sector or NGOs. When asked which part of the world their job was focused, the respondents reported all continents (excluding Antarctica) along with thirty-seven specific countries.

Based on analysis of the survey data, IFPTI and RAPS again revised the set of competencies. This new revision was sent out to the Expert Panelists for vetting purposes.

Panelists were given one additional opportunity to revise/edit any or all of the competencies. Feedback was limited; however, some minor revisions were made and another draft version of the competency set was created. This new revision served as the cornerstone for a face-to-face meeting with the Expert Panelists in early September.

In-Person Consensus Meeting

The two-day meeting with the Expert Panels was held on September 4th and 5th at the Hilton Rockville (MD, USA). In attendance were 8 panelists on the food safety side, and 9 panelists from the medical product side. Also in attendance were Mary Morrison from FDA, 5 IFPTI staff members, and 5 RAPS staff members. The meeting was led by Dr. Craig Kaml, IFPTI's Vice President of Curriculum.

On the first day of the meeting, the competency framework for Basic Level regulators working in the food and/or the medical product sector was finalized. Competencies were categorized into the following groups:

- Core General (both food and medical product): knowledge, skills, and abilities common to successful performance across all subject matters.
- Core Technical (both food and medical product): knowledge, skills, and abilities related to subject matter pertinent to this profession (e.g., microbiology, chemistry, regulations, etc.).
- Food Specific: knowledge, skills, and abilities essential for employees of government agencies with authority to regulate food (including animal feed).
- Medical Product Specific (Regulatory Information and Strategy): general regulatory knowledge, skills, and abilities essential for employees of government agencies with authority to regulate medical products.
- Medical Product Specific (Pre-approval / Approval): knowledge, skills, and abilities essential for employees of government agencies with authority to regulate medical products with a focus on the pre-approval and approval phases.

- Medical Product Specific (Post-approval): knowledge, skills, and abilities essential for employees of government agencies with authority to regulate medical products with a focus on the post-approval phase.

On the second day of the Expert Panel meeting, the list of competencies was used by experts to identify specific job functions and topic areas dealt with by regulators of food and medical products. This list of topics was categorized and refined, resulting in a draft curriculum framework for Basic Level regulators working in the food and/or medical product sector. Curriculum content areas were classified accordingly:

- Core content (Compliance, Surveillance & Enforcement)
- Core content (Information Management)
- Core content (Professional Skills)
- Core content (Public Health Principles)
- Core content (Regulatory Framework / Organizational Awareness)
- Core content (Science)
- Food specific (Compliance, Surveillance & Enforcement)
- Food specific (Food Safety)
- Food specific (Regulatory Framework)
- Food specific (miscellaneous: Emerging Issues, Food Security, GMOs, Risk Analysis)
- Medical Product specific (Regulatory Framework)
- Medical Product specific (Application Review & Product Registration)
- Medical Product specific (Product Development)
- Medical Product specific (Compliance, Surveillance & Enforcement)
- Medical Product (miscellaneous: Emerging Issues)

After the face-to-face meeting, both the Competency Framework and the Curriculum Framework (both included as attachments to this report) were sent back to the Expert Panelists for a final review. Comments and edits were received from some of the Expert Panelists, and revisions were made accordingly. Finalized versions of the frameworks were created by the end

of September, along with a set of definitions for each of the curriculum content areas that was reviewed by the Expert Panel. (These definitions are also attached to this report.)

Capacity-Building Tools

A number of regulatory capacity-building tools already exist (see Table 2 as well as Practical Guidance for Conducting a Review based on the WHO Data Collection Tool for the Review of Drug Regulatory Systems – World Health Organization). All use a similar approach to evaluate capacity building needs that can be identified based on the difference between the current capacity and the desired future capacity. The tools also address capacity at different, but closely related, levels: the system or context in which organizations, groups and individuals operate; organizations and groups within the system; and individuals within organizations and groups. This project focuses on the individual level since it addresses competencies involving worker knowledge and skills.

Table 2. Capacity-Building Tools

Tool and Web Link	Developed By
Tool for the Evaluation of the Performance of Veterinary Services	**World Organization for Animal Health (OIE)**
Performance, Vision and Strategy (PVS) for National Veterinary Services	**Inter-American Institute for Cooperation on Agriculture (IICA)**
Strengthening national food control systems. Guidelines to assess capacity-building needs.	**Food and Agriculture Organization of the United National (FAO)**
Performance, Vision and Strategy (PVS) for National Food Safety Services	**IICA**
Performance, Vision and Strategy (PVS) for National Plant Protection Organizations	**IICA**
Guide to Assess Biosecurity Capacity	**FAO**

Regulatory Workforce Competency Gap Approach

A competency and training need is a gap between "what is" (the present) and "what should be" (the desired future). IFPTI and RAPS sought to create a process for assessing competency and training needs that is compatible with the WHO and the FAO tools so that it could be incorporated into those models as a sub-module. The process considers the present employee competency levels of the national food or medical products control system as well as guides the building of a plan to address employee professional development needs based on the competency and curriculum frameworks that were created through this project.

Assessing Regulatory Workforce Competency and Training Needs in Food and Medical Product Safety

Consistent with WHO and FAO approaches, it is recommended that an appropriate team manage the gap analysis process and define its scope. Figure 2 below represents the process from beginning to end, although the process is one that is ongoing, depending on agency/organizational needs.

Figure 2. Assessment Process

Beginning with an individual competency self-assessment (Step 1 in Figure 2), the team should then aggregate individual assessments (Step 2) and seek agency input to determine the "as is" levels of worker competency (Step 3). A gap analysis should then take place by identifying the current competency levels against desired levels (Step 4), followed by use of the crosswalk document included in this report. The crosswalk (Step 5) allows agency personnel to identify potential training areas that can address competency gaps. The crosswalk will also allow agencies to prioritize development needs that should be addressed in the short, medium, and long- terms (Step 6). At this point, an agency can identify education and training resources (Step 7) that can be utilized to address competency gaps, and a Professional Development Plan (Step

8) can be created by the agency. The process culminates in a "treatment" - the actual scheduling of training or education that can be revisited annually, or as often as the regulatory agency deems appropriate. Future work is needed to coordinate the identification and development of appropriate curricula, including training and educational content for this community. The content should be competency-based and a method should be employed to have a body review courses or other treatments for quality and consistency against professional standards. Assessment and evaluation components of an overall approach should also be carefully considered.

Program Pilot

A determination was made for this phase of the project to "pilot" the competency assessment survey tool (Step 1 of the overall process). An assessment form was created and converted to an online survey using Survey Monkey. The survey, called the Global Competency Self-Assessment, is used to obtain self-evaluation responses from food or medical product personnel within a work unit. The facilitator or manager instructs individuals within the work unit to independently complete the 96 point survey that can be provided online or by using hard copies. The surveys should be completed anonymously since the goal is to implement an agency- or unit-wide plan for all individuals performing like duties. While some of the survey applies to either food or medical products staff, other parts apply to one or the other depending on the responder's role. The survey tool is composed of competency statements from the Competency Framework and for each statement, the responder rates their perceived level of attainment on a scale of 1-5 accordingly:

1. **No Ability:** You have absolutely no knowledge or experience related to this skill.
2. **Limited Ability:** You have a common knowledge or basic understanding of this skill, and you may even have limited classroom or on-the-job experience related to the skill. However, you are expected to need help when performing this skill.

3. **Intermediate Ability:** You are able to successfully complete tasks in this competency as requested. Help from an expert may be required from time to time, but you can usually perform the skill independently.
4. **Advanced Ability:** You can perform the actions associated with this skill without assistance. You are certainly recognized within your immediate organization as "a person to ask" when difficult questions arise regarding this skill.
5. **Expert Ability:** You are a known expert in this area. You can provide guidance, troubleshoot, and answer questions related to this area of expertise and the field where the skill is used.

(There is also a Not Applicable answer choice [N/A], where the individual is not required to apply or demonstrate this competency and/or the competency is not applicable to his or her position.

A Senior Management Official from the Zambia Department of Veterinary Science, Ministry of Agriculture and Livestock agreed to have staff of the food safety inspection program of that agency perform the self-assessment survey. This work unit is only responsible for food protection activities (not medical products) so only the applicable portions of the survey applied (41 items). The online version was utilized and seven employees responded to the competency questions and completed the survey. A summary spreadsheet was prepared as is attached to this report.

For this phase of the project, Phase I, the pilot addressed the mechanics of this process. Findings of the pilot include:

- The online version was chosen since agency employees had ready access to computers in the normal course of their work.
- On-line access to the tool was convenient and there were no apparent problems in completing the assessment tool.
- Individuals were able to complete the survey in less than 30 minutes.
- Response turnaround time was less than one week – indicating that proper guidance and instruction was given by the manager to complete data capture.

- Here are the average ratings for each section:
    - Core General Competencies: 4.38
    - Core Technical Competencies: 4.27
    - Food-Related Competencies: 4.31
- A point of demarcation appeared easy to establish – 13 of 41 competencies were rated below 4.00 – these appeared to be primary candidates for further review/ gap analysis.

Overall ratings would indicate that this work unit already has high levels of competency. However, responders on surveys of this type tend to rate themselves high. Therefore, further study should be undertaken in future pilots or capacity-building assessments to gather additional data to compare employee competency indicators such as performance indicators, training/ education transcripts, certifications, etc. This also places importance on the assessment ratings of – and data analysis by – the work unit manager(s). (In the Zambia data spreadsheet, additional columns were added for a supervisor rating for each individual. This will be conducted during Phase II of the project. The following additional steps are planned during the pilot portion of Phase II:

- Aggregation and evaluation of employee and manager assessment responses.
- Analysis of competency gaps/ needs.
- Prioritization of competencies needing improvement.
- A cross-walk of competencies needing improvement against curriculum content areas.
- Identification methods for employee development needs.
- Identification of factors that should be considered in a review of the applicability of training/ educational resources to aid employee development.
- Methods of building work unit, employee development plans.
- Treatment considerations for implementing development plans.