

## ANNEX B

### Qualified Person Qualification and Credential Requirements

Type of Establishment	Qualified Person	Qualification/Requirement
<b><u>CDRR</u></b> Drug Manufacturer, Trader and Distributor (wholesaler, importer, exporter), CROs and Sponsors, drug outlet, and RONPD	Registered Pharmacists (RA 10918)	a. Professional Regulation Commission (PRC) Identification Card (ID) b. Seminar/training certificate, learning and development activities on drug safety, quality, and efficacy and other applicable trainings (e.g., Training for Pharmacy Assistant, Basic and Advance Course on Good Clinical Practice for CROs/ sponsors c. Proof of termination of employment if previously connected with another pharmacy/establishments
<b><u>CFRR</u></b> Food Manufacturer, Trader and Distributor (Wholesaler, Importer, Exporter)	Preferably a graduate of food-related courses including but not limited to food technology, food and nutrition, chemistry, microbiology, chemical/sanitary engineering, veterinary medicine, fisheries, agriculture (RA 10611).	Seminar/training certificate on food safety, GMP or HACCP given by the academe, WHO, FAO, NGOs, cooperative, food industry organizations, professional organizations, or the FDA Academy
<b><u>CDRRHR</u></b>  • Retailers of Medical Devices	Company Regulatory Officer at least college graduate	Diploma
• Retailers of ophthalmic lenses, prisms, contact lenses and their accessories and solutions, low vision aids, and similar appliances and devices wherein the dispensing is governed by RA 8050 or the “Revised Optometry Law of 1995”	Optometrist	PRC ID
• Health-Related Device Manufacturer, Trader, and Distributor (Wholesaler, Importer, Exporter) of:	Graduate of engineering courses preferably chemical, sanitary, civil, and mechanical, or other science courses relevant to the device to be distributed	PRC ID for professions with Board/Licensure examination or Diploma for profession without Board/Licensure examination. For water treatment devices, a

<ul style="list-style-type: none"> <li>- Equipment or devices used for treating sharps</li> <li>- Pathological and infectious wastes</li> <li>- Water treatment systems</li> <li>- Water treatment devices</li> </ul>		copy of diploma shall be provided.
<ul style="list-style-type: none"> <li>• Medical Device Manufacturer, Trader, and Distributor (wholesaler, importer, exporter) of: <ul style="list-style-type: none"> <li>- Radiation-emitting devices</li> <li>- In-vitro diagnostic reagents</li> <li>- Refurbished medical devices</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>a. Registered professional or graduates in the field of health profession such as Pharmacy, Nursing, Medical Technology, Dentistry, Radiologic Technology, Medicine, Physical Therapy, and other allied science courses relevant to the device to be distributed</li> <li>b. Engineering profession that includes but not limited to EE, ECE, ME, CoE, CHE, SE, Computer Science, and Chemistry</li> </ul>	<ul style="list-style-type: none"> <li>a. Certificate of Attendance to seminars, training, learning and development activities on device safety, quality and use given by the academe, industry, organization, professional organization, National Regulatory Authorities, international organization which includes the WHO and ISO.</li> <li>b. PRC ID for professions with Board/Licensure exam or Diploma for profession without Board/Licensure exam</li> </ul>
<b><u>CCHUHSRR</u></b>		
<ul style="list-style-type: none"> <li>• Manufacturer of Cosmetic establishments</li> </ul>	Registered Chemist, Chemical Engineer, or Pharmacist	Valid PRC ID
<ul style="list-style-type: none"> <li>• Trader and Distributor (wholesaler, importer, exporter) of Cosmetic establishments</li> </ul>	Registered professional or graduates in the field of allied health, chemistry, chemical engineering, or cosmetic science with verifiable, recognized, and updated trainings on the safety, quality, and use of cosmetics	<ul style="list-style-type: none"> <li>a. Valid PRC ID for professions with board/licensure exam or Diploma for professions without board/licensure exam; and</li> <li>b. Certificate and copy of program of activities as proof of attendance to seminars, trainings, learning and development activities on cosmetic safety, quality, and use, given by the academe, industry organization, professional organization, National Regulatory Authorities, international organizations</li> </ul>
	<b>For HUHS</b> - Registered professional or graduates in the	<ul style="list-style-type: none"> <li>a. Valid PRC ID for professions with board/licensure exam or</li> </ul>

<ul style="list-style-type: none"> <li>Manufacturer, trader, and distributor (wholesaler, importer, exporter) Household/Urban Hazardous Substances</li> </ul>	field of allied health, chemistry, or chemical engineering with verifiable, recognized, and updated trainings on the safety, quality, and use of HUHS	Diploma for professions without board/licensure exam; and b. Certificate of copy of program of activities as proof of attendance to seminars, trainings, learning and development activities on HUHS safety, quality, and use, given by the academe, industry organization, professional organization, National Regulatory Authorities, international organizations
	<b>For HUP</b> - Registered professional or graduates of Pharmacy, Chemistry, Chemical Engineering, Toxicology, Veterinary Medicine, Agricultural Biotechnology (Entomology) and Entomology	Valid PRC ID for professions with board/licensure exam or Diploma for professions without board/licensure exam
	<b>For TCCA</b> - Bachelor's degree with verifiable, recognized, and updated trainings on the safety, quality, and use of TCCA	a. Valid PRC ID for professions with board/licensure exam or Diploma for professions without board/licensure exam; and b. Certificate and copy of program of activities as proof of attendance to seminars, trainings, learning and development activities on TCCA, safety, quality, and use, given by the academe, industry organization, professional organization, National Regulatory Authorities, international organizations

When applicable,  
the following information may be requested by the FDA in the Application Form

Drug Manufacturer	a. Production Manager/head b. Quality Assurance Manager/head c. Quality Control Manager/head d. Authorized person for batch release e. Pharmacovigilance officer
Food Manufacturer	a. Production Manager/head b. Quality Assurance Manager/head c. Quality Control Manager/head d. Food Safety Officer

	e. Any designated senior technical personnel
Medical Device Manufacturer	a. Production Manager/head b. Quality Assurance Manager/head c. Quality Control Manager/head
Cosmetic and HUHS Manufacturer	a. Production Manager/head b. Quality Control and/or Assurance Manager/head c. Product Safety Assessor