

ANNEX C

QUALIFIED PERSON QUALIFICATIONS AND CREDENTIAL REQUIREMENTS

Type of Establishment	Qualified Person	Qualification/Requirement
<p><u>CDRR</u></p> <p>Drug Manufacturer, Trader, and Distributor (wholesaler, importer, exporter), drug outlet, and RONPD</p>	<p>Licensed and Registered Pharmacists</p>	<p>a. Professional Regulation Commission (PRC) Identification Card (ID);</p> <p>b. Certificate of Completion issued by the FDA or seminar/training certificate on drug safety, quality, and efficacy and other applicable trainings, Basic and Advance Course on Good Clinical Practice for CROs/ sponsors.</p>
<p>Clinical Research Organizations (CROs) and Sponsors</p>	<p>a. Licensed and Registered Pharmacists (R.A No. 10918)</p> <p>b. PRC-Licensed allied (medical) sciences such as Medical Doctor and Medical Specialist</p>	<p>Such training or seminar must have been conducted not more than two (2) years reckoned from the date of submission of application for LTO; and</p> <p>c. Proof of termination of employment if previously connected with another pharmacy/establishments.</p>
<p><u>CFRR</u></p> <p>Food Manufacturer, Trader, and Distributor (Wholesaler, Importer, Exporter)</p>	<p>For small, medium, large FBOs:</p> <p>PRC-registered for the following courses: food technology, food and nutrition, chemistry, chemical/sanitary engineering, veterinary medicine, fisheries, agriculture; or certification for microbiology and other food-related courses not requiring PRC registration.</p>	<p>a. Valid PRC ID</p> <p>b. Seminar/training certificate on food safety, GMP, HACCP, and other food safety related regulations given by the DOH-FDA, or FDA recognized government institutions, the academe, professional associations, and third-party service providers conducted within 2 years from the date of filing of application.</p>

	<p>For micro FBOs: Graduate of the following courses: food technology, food and nutrition, chemistry, microbiology, chemical/sanitary engineering, veterinary medicine, fisheries, agriculture and other food-related-courses</p>	<p>a. Valid Diploma; and b. Seminar/training certificate on food safety, GMP, HACCP, and/or other food safety related regulations given by the DOH-FDA, or FDA recognized government institutions, the academe, professional associations, and third-party service providers conducted within 2 years from the date of filing of application.</p>
<p><u>CDRRHR</u> 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”.</p>	<p>Registered professional or graduate of allied health courses including but not limited to Optometry, Doctor of Medicine, Pharmacy, and vocational course or other courses relevant to the medical devices being handled.</p>	<p>At least graduate of vocational courses and profession with or without Board/Licensure examination relevant to the medical device being handled:</p> <p>a. PRC ID for professions with Board/Licensure examination; b. Diploma or Certificate (e.g., TESDA, Other government or private accredited training providers) for vocational courses relevant to the medical device being handled; or c. Diploma for profession without Board/Licensure Examination</p>
<p>Manufacturer, Trader, and Distributor (Wholesaler, Importer, Exporter) of health-related devices specifically:</p> <p>a. Equipment or devices used for treating sharps, pathological and infectious wastes; and b. Water purification treatment devices and/or systems</p>	<p>Graduate of engineering courses preferably chemical, sanitary, civil, and mechanical, or other science courses relevant to the device to be distributed</p>	<p>a. PRC ID for professions with Board/Licensure examination; or b. Diploma for profession without Board/Licensure Examination</p>

<p>Manufacturer, Trader, and Distributor (Wholesaler, Importer, Exporter) and Retailer of medical devices</p>	<p>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.</p> <p>b. Engineering profession that includes but not limited to EE, ECE, ME, CoE, CHE, SE, Computer Science, and Chemistry</p>	<p>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; and</p> <p>b. PRC ID for professions with Board/Licensure exam or Diploma for profession without Board/Licensure exam.</p>
<p><u>CCHUHSRR</u></p> <p>Manufacturer of Cosmetic establishments</p>	<p>Registered Chemist, Chemical Engineer, or Pharmacist</p>	<p>Valid PRC ID</p>
<p>Trader and Distributor (wholesaler, importer, exporter) of Cosmetic establishments</p>	<p>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</p>	<p>a. Valid PRC ID for professions with board/licensure exam or Diploma for professions without board/licensure exam; and</p> <p>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.</p>
<p>• Manufacturer, trader, and distributor (wholesaler, importer, exporter) Household/Urban Hazardous Substances</p>	<p>For HUHS - Registered professional or graduates in the field of allied health, chemistry, or chemical engineering with verifiable, recognized, and updated trainings on the safety, quality, and use of HUHS</p>	<p>a. Valid PRC ID for professions with board/licensure exam or Diploma for professions without board/licensure exam; and</p>

		<p>b. Certificate and 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.</p>
	<p>For HUP - Registered professional or graduates of Pharmacy, Chemistry, Chemical Engineering, Toxicology, Veterinary Medicine, Agricultural Biotechnology (Entomology) and Entomology</p>	<p>a. Valid PRC ID for professions with board/licensure exam or Diploma for professions without board/licensure exam; and</p> <p>b. Certificate and copy of program of activities as proof of attendance to seminars, trainings, learning and development activities on HUP safety, quality, and use, given by the academe, industry organization, professional organization, National Regulatory Authorities, international organizations.</p>
	<p>For TCCA - Bachelor's degree with verifiable, recognized, and updated trainings on the safety, quality, and use of TCCA</p>	<p>a. Valid PRC ID for professions with board/licensure exam or Diploma for professions without board/licensure exam; and</p> <p>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.</p>

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