



GUIDELINE ON EDUCATION AND TRAINING FOR STAFF OF NMRA

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NATIONAL MEDICINE REGULATORY AUTHORITY
No.120, Norris Canal Rd, Colombo 01000, Sri Lanka

GUIDELINE ON EDUCATION AND TRAINING FOR STAFF OF NMRA

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1. PURPOSE

The purpose of this procedure is to describe the processes used to ensure all the staff categories of NMRA have the knowledge, experience, skills, and behaviours to perform regulatory activities and tasks associated with their role. These processes ensure high standard level of regulatory processes to fulfill the requirements of MRA Act

2. SCOPE

This procedure covers the education and training requirements for staff of NMRA and personnel who carry out specific regulatory activities such as Authorized Officers, Members of Committees established under NMRA Act.

3. DOCUMENTATION MANAGEMENT SYSTEMS

NMRA requires documentation systems to maintain education and training records in accordance with QMS of NMRA.

4. GLOSSARY

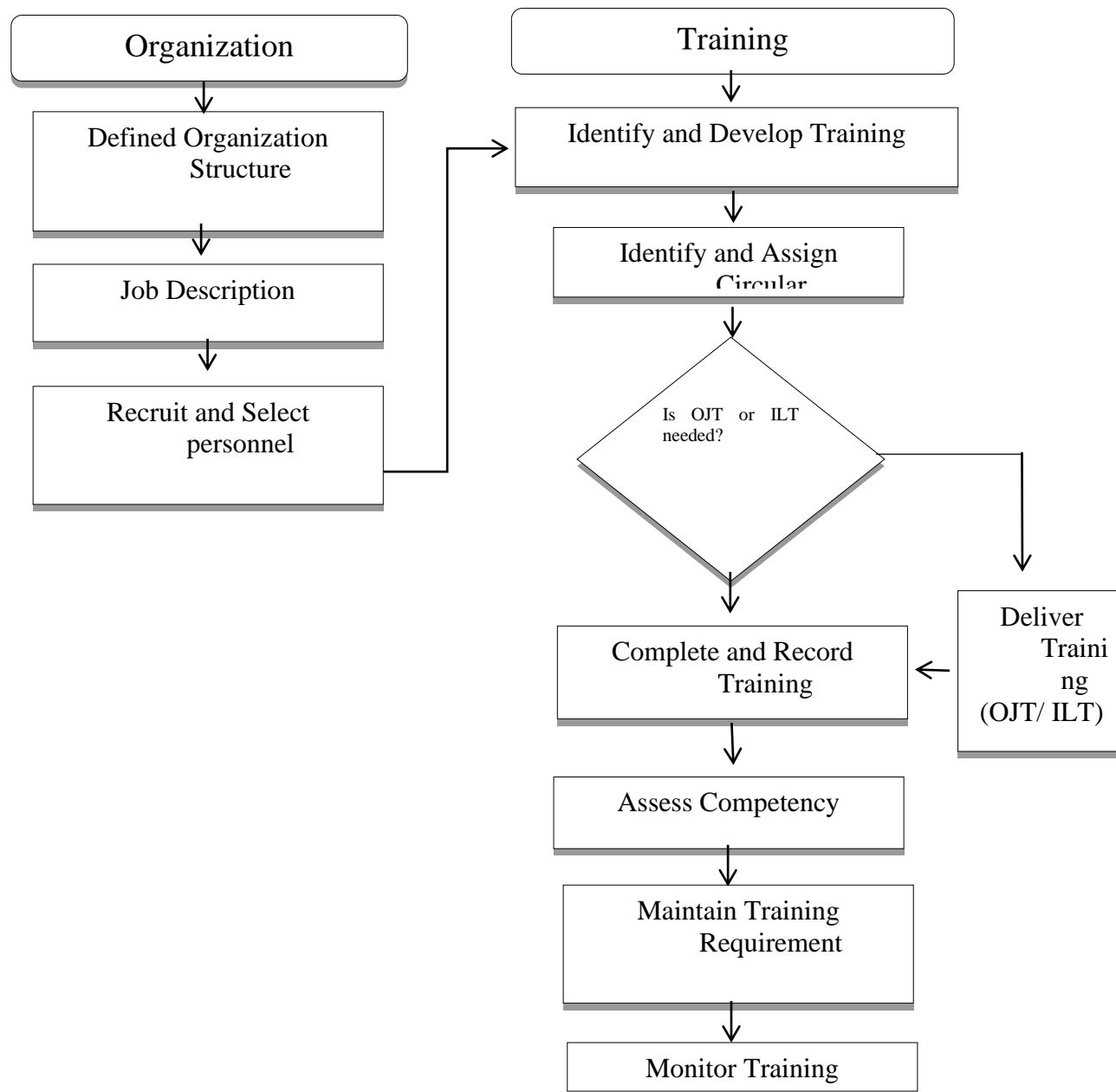
Competency	A set of knowledge, skills and behaviours required to effectively perform a task or job.
Competency Assessment	A process that measures a person's ability to apply the skills and behaviours required in performing a specific task or job.
Curriculum	A grouping of one or more training items. Plural is Curricula.
Effective	Approved document is released for use.
Expected Training	Training that ensures personnel have the required skill, process or behavioural training to perform their job. 100% completion by the due date is expected.
Instructor Led Training (ILT)	Face to face delivery of training by an instructor (trainer, SME or trained personnel) as a one to one training or in a classroom setting which may include completion of an assessment questionnaire.
Mandatory Training	Training that ensures personnel understand legislations and regulations related to the conducts of NMRA and its functions. NMRA expects 100% completion by the due date.
On the Job Training (OJT)	A hands-on training event facilitated by a trainer in the work setting. Evaluation of competency conducted at the workplace task is performed OJT only applies where the performance of each step of the task can be physically observed
Self-Certification	Training conducted by self-study (paper or computer based) and certification (manual or electronic signature) of completion.
Subject Matter Expert (SME)	A person who is an authority and has expert knowledge about a topic, or process.
Trainer	Person with specific skills and knowledge who is qualified to train others on a specific task.

5. ABBREVIATIONS

HRD - Human Resource Division
HED - Head of Education and Training Division
SMEs - Subject Matter Experts

6. PROCESS FLOW & INSTRUCTIONS

Process Flow



Step No.	Instruction	Responsible
ORGANISATION		
6.1 Define the Organizational Structure Organization structures are required to ensure the staff involved with regulatory activities has the correct roles and number of personnel to perform the required activities.		
6.1.1	Ensure adequate number of personnel are available to support regulatory activities	CEO
6.1.2	Create an Organization chart Identify competent personnel to perform activities for roles during absences and for delegation of tasks	
6.3	Review the organization charts to ensure responsibility placed on one person is not so extensive.	
6.2 Manage Job Descriptions Job descriptions are required for personnel involved in regulatory activities and form the foundation for processes such as recruitment and selection, training and performance management.		
6.2.1	Create job descriptions using the Job Description template aligned to the organization chart. Define the specific duties of the role and include: <ol style="list-style-type: none"> 1. job title and department within the organization 2. position within the organization and reporting line 3. specific duties of the role and specialist roles 4. authority, responsibilities and competencies of the job <ul style="list-style-type: none"> o key responsibilities o scope of accountability o experience required 	HRD
6.2.2	Approve the job description to indicate the accuracy of the job role and responsibilities. Provide all personnel with a copy of their job description.	HRD
6.2.3	Sign and date the job description to indicate receipt.	Personnel
6.2.4	Retain job descriptions as per Quality system	HRD
6.2.5	Review and update job descriptions when changes in responsibilities are identified at role, team or organizational level or at minimum every 2 years.	HRD
6.3 Recruit and Select Personnel Define the recruitment and selection criteria based on the job description with Human Resources (HR). Tools and templates for recruitment and selection will be provided by the		

HR recruiter. HR will support the manager during the recruitment and selection processes, and retention of consultant information.		
6.3.1	Recruit personnel to fill roles, ensure they have the qualifications, experience and competence for the role.	HRD
6.3.2	Ensure pre-employment and pre-engagement screening is completed before making an employment offer. (SOP-) Identify additional requirements for personnel whose job roles includes critical or sensitive activities, for example additional screening for personnel working with controlled substances.	HRD
6.3.3	Confirm consultants who provide services and external training providers have the education, training and experience on the subject. Retain the consultants name, business address, qualifications (for example, certifications, curriculum vitae) and the service provided.	HRD

6.4 TRAINING

6.4 Identify and Develop Training

Develop training to align to job responsibilities, accountabilities and experience required to perform the role.

Determine the training delivery method to ensure effectiveness of the training. If learning technology, for example video, virtual reality, is implemented to replace or supplement on the job training, competency assessment must be demonstrated and documented. Refer to Section 6.8.

6.4.1	Identify training requirements based on: 1. job description 2. common training needs 3. role specific training needs 4. tasks and/or process training	HRD
6.4.2	Conduct annual refresher training. Example topics to consider are: 1. changes in regulatory requirements 2. audit and management monitoring (self-inspection) findings	HED
6.4.3	Determine the preferred Training Delivery Method Training delivery methods are: 1. Read and Understand self-certification (paper or electronic) 2. Computer based training (e-learning) 3. Instructor Lead Training (ILT) (classroom training) 4. On the Job Training (OJT) 5. Learning technology (for example, video, virtual reality)	HED
6.4.4	Identify subject matter experts to develop the training content.	HED

6.4.5	<p>Develop training and ensure:</p> <ol style="list-style-type: none"> 1. there is an owner assigned with appropriate expertise on the topic 2. the content has a clear scope and learning objectives 3. the content is accurate, complete, aligned to the specific process or procedure 4. the content meets the capability needs of its intended audience 5. the content is aligned with regulatory and legal expectations and associated procedures, if applicable 6. it includes a competency assessment, if applicable (Refer APPENDIX 7 for SOP Assessment Form template) 	HED
6.4.6	Assign a version number, effective date and review period (maximum of 3 years) to the training materials.	QM
6.4.7	<p>Approve the training.</p> <p>Centrally developed and approved training, for example, QMS training does not require local approval unless it has been customized. If it has been customized locally, follow Steps 6.4.4 to 6.4.9.</p>	CEO
6.4.8	Retain training content per quality manual	
6.4.9	Review training content when associated procedures are revised	HED
<p>6.5 Create and Assign Curricula</p> <p>Training must be assigned to all personnel involved with regulatory activities based on the job description and role requirements.</p>		
6.5.1	<p>Create curricula (training plan or training matrix) based on training requirements for Induction the requirements of the role or task (Annexure 5) (see step 6.4.1).</p> <p>Include both initial and refresher training, along with periodic retraining, if applicable.</p> <p>The departmental induction program for new joinee shall be prepared by the training coordinator and approved by the HRD (Annexure 3)</p> <p>New joinee shall fill the induction program summary report (Annexure 4) as per the schedule and shall we approved by the line HRD after completion of program.</p> <p>Induction shall be completed within 60 calendar days. If this is not achieved in exceptional cases, this should be documented in the Annexure 4 with a justification.</p> <p>For training associated with documentation, due dates need to allow for training to be completed prior to the effective date.</p> <p>New personnel / role change in personnel may have an extended training due date for completion provided the individual does not perform tasks unsupervised.</p>	HRD
6.5.2	Identify a curriculum owner.	HRD

6.5.3	Assess the training needs of personnel after long term absence (greater than 6 months). Complexity/criticality of the task or process and level of expertise must be considered.	
6.5.4	Notify the HED if a task or process hasn't been performed for a period or when additional training is required.	Personnel
6.5.5	Assign curricula to personnel.	
6.5.6	If training is read and understand or computer based, go to step 6.7.	

6.6 Deliver Training (OJT and ILT)

Trainers need to have the appropriate skills and/or experience to deliver training. Persons may complete the Train the Trainer training as appropriate.

Trainers, Subject Matter Experts (SMEs) or trained persons may deliver training.

6.6.1	Identify NMRA personnel for the role of trainers based on: <ul style="list-style-type: none"> • competency in the subject, task or procedure • ability to effectively transfer knowledge and provide feedback • effective communication skills and willingness to assist others • ability to coach • availability to deliver training 	HRD
6.6.2	Develop OJT training plans that include the following steps: <ul style="list-style-type: none"> • trainer demonstrates the task • trainee practices the task with coaching under the supervision of the trainer • trainee performs tasks, under the supervision of the trainer without coaching. • trainer assesses the trainee's knowledge, understanding and capability of performing the task 	
	Deliver the training.	
	Document training completion and assessment.	
	Retain training content, training records and assessment Retain training content, training records and assessment (GRS113) (Appendix 6 and Appendix 7). (Appendix 6 and Appendix 7).	

6.7 Complete and Record Training

Training can be completed and recorded or maintained with a paper system or electronic system. If a paper system is used, a personnel or group training file can be created.

6.7.1.	Complete and record training by the due date. Regularly review training plan for assigned training.	Personnel
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6.7.2	Provide personnel with an appropriate amount of time to ensure they can effectively complete training on time. This is particularly important for read and understands training (self-certification), training of new personnel or when personnel change roles.	HRD
6.7.3	Personnel must not work unsupervised until required training and satisfactory assessments have been completed and recorded.	Personnel and Trainer
6.7.4	During training, any task that requires a signature must be signed by the person being trained and the trainer	Personnel and Trainer
	Retain training records and assessment. (Appendix 6 and Appendix 7).	

6.8 Assess Competency

As determined by the Training Delivery Method, assess the training to ensure training content was understood. Competency assessments can be conducted through questionnaires during training (ILT), quizzes after read and understand, and observing a task or process being performed during training (OJT).

6.8.1	Apply a minimum pass mark of 75% for questionnaires or quizzes. No more than 3 retakes before additional intervention is applied, for example, coaching.	Trainer
6.8.2	Include OJT assessments for personnel who routinely perform visual inspections to ensure they can carry out the function and are able to detect defects or errors against a standard.	HRD
6.8.3	Document and record assessment	Personnel and Trainer
6.8.4	If personnel did not achieve satisfactory results during the assessment: <ul style="list-style-type: none"> • notify the person of the results • obtain recommendations from the trainer • develop actions to address training gaps • determine next steps 	HRD
6.8.5	Retain assessments as per the quality system	

6.9 Maintain Training Requirements

Training requirements need to remain current based on changes in the functions, regulations and changes in international guidelines.

6.9.1	Conduct a training performance review with NMRA personnel at minimum, annually and include: <ul style="list-style-type: none"> • completion of training against the curricula • any training (for example, curriculum assignments) or competency gaps against the role requirements 	HED
6.9.2	Update curricula based on changes in business and operational	HED

	needs including: <ul style="list-style-type: none"> • changes to the role • audit findings • external and internal requirements and changes, for example regulatory, new legislation, company policies • new or upgraded systems • new or revised methods or procedures • quality deviations, non-conformances, product incidents, recalls 	
6.9.3	Review curricula content at minimum every 2 years for accuracy and completeness including: <ul style="list-style-type: none"> • additional or new training requirements • removal of unnecessary or obsolete training Document the output from the curriculum review either manually or electronically and address any required changes required.	HED
6.9.4	Retain curricula review as per quality system	HED
6.10 Monitor Training Performance Conduct a review of compliance training to determine the effectiveness.		
6.10.1	Monitor completion of training against the due date. Address overdue training with personnel.	HED
6.10.2	Perform an annual review of training to evaluate effectiveness of the training process and review. Retain report as per as per quality system	HED

7. ROLES AND RESPONSIBILITIES

Leadership Team	<ol style="list-style-type: none"> 1. Define the organization 2. Create and maintain organization charts
HRD	<ol style="list-style-type: none"> 1. Support recruitment and selection of personnel 2. Maintain consultant information 3. Create, update and approve job descriptions, recruit personnel 4. Identify SMEs to develop training 5. Identify trainers 6. Define training requirements 7. Monitor overdue training 8. Act upon unsatisfactory training assessment results 9. Ensure individuals do not perform any activities unsupervised unless training has been completed and they are competent to do so 10. Identify curriculum requirements 11. Retention of training content, records and assessments 12. Conduct training performance reviews

Personnel	<ol style="list-style-type: none"> 1. Complete and record training by the due date 2. Complete training prior to executing a task 3. Support the role as Trainer as needed
SME	<ol style="list-style-type: none"> 1. Develop training content and assessments 2. Ensure training materials are current and compliant with regulatory requirements and procedures. 3. Deliver, record and assess training 4. Perform the annual effectiveness review
Trainer	<ol style="list-style-type: none"> 1. Deliver, record and assess training 2. Contribute to the development of the training content and assessment
Quality Team	<ol style="list-style-type: none"> 1. Approve training 2. Conduct annual GMP/GDP refresher training 3. Manage GMP/GDP training processes 4. Perform an annual review of training to evaluate effectiveness of the training process
Quality Council	<ol style="list-style-type: none"> 1. Monitor training performance 2. Resolve any escalation items

8. REFERENCES

Reference Description	Reference No
1. Document Management and Control	xx
2. Organization, Personnel Management and Training	xxx
3. QMS Implementation	xxxx
4. Pre-employment / Pre-engagement Screening	xxxxx
5. Mandatory and Expected Training	xxxxxx

APPENDIX 1: TRAINING DELIVERY METHOD

Training Delivery Approach Minimum
Instructor Led Training <u>or</u> On-the Job Training <u>or</u> Learning technology with assessment <u>or</u> Read and Understand with self-certification (written document, computer learning/e-learning) and Assessment Questionnaire <u>or</u> Assessment Questionnaire

APPENDIX 2: STANDARD OPERATING PROCEDURE READ & UNDERSTOOD FORM

Departmental Induction Program

Name			
Employment No.			
Designation			
Division			
Date	Meeting Time	Topic	Contact Person

Prepared by (Training Coordinator)

Approved by

APPENDIX 4- TEMPLATE FOR INDUCTION PROGRAM SUMMARY REPORT

Induction Program Summary Report

Name				
Employment No.				
Designation				
Department				
Date	Meeting Time	Topic	Contact Person	
			Name	Sign/Date

Remark by New Joinee:

Sign & Date:

Extension (if any):

Justification-

Remark by HRD

Sign & Date

APPENDIX 5- TEMPLATE FOR TRAINING MATRIX

[illegible]

Revision history

Version no.	Changes done	Revision date

Y- Training is required

N- Training is not required

APPENDIX 6- TRAINING ATTENDANCE FORM

Training Item		
Location		
Date		

Trainer ID	Name	Signature

Serial No	Name	Division	Signature

APPENDIX 7- TRAINING ASSESSMENT FORM (SOP AND ON THE JOB TRAINING)

Trainee Name	Department	Signature	Date

Item	Questions (Multiple Choice or True/False)	Answer
1	Add local assessment requirements	
2		
3		
4		
5		
6		
7		
8		
% Correct -	Assessment Criteria = 75%	Competent/ Not Yet Competent (<i>delete one</i>)

Trainer/Assessor	Signature	Date

APPENDIX 8 - INDUCTION PROGRAM FOR NEW STAFF

The induction program lists suggested activities to be covered from day one through to the end of probation.

SESSION	SUGGESTED CONTENT OF SESSION
Introduction to the NMRA and work area <i>Person Responsible – CEO</i>	<ul style="list-style-type: none">• Mission, Vision, Objectives of work area• All key operational and social areas to be visited.
Introduction to other members of staff <i>Person Responsible – Administrative officer (AO)</i>	<ul style="list-style-type: none">• Go through organisation chart• Discuss roles and responsibilities of staff in general terms.
Introduction to the other teams within the Work area (if appropriate) <i>Person Responsible – AO</i>	<ul style="list-style-type: none">• Purpose/Activities of the other teams/work areas• How the team fits in to the work area• How the work area fits into the University
Terms and Conditions <i>Person Responsible – Head. NMQUAL/ CP/ C.FD&I / AO</i>	<ul style="list-style-type: none">• Ensure new start has viewed and understood information contained in the Information for New Employees this contains important information on terms and conditions.
Performance Standards <i>Person Responsible – Focal Points of Each Division</i>	<ul style="list-style-type: none">• Outline specifics of job role – (job description)• Define goals, objectives, and expectations• Review probation and performance and development review / appraisal process.
Culture of the Work area <i>Person Responsible –Nominee</i>	<ul style="list-style-type: none">• Make new start aware of local arrangements regarding hours of work, holiday requests, sickness procedure, after hours working, dress code, lunch arrangements, etc.• Other procedures e.g. internet and e-mail usage, transportation and parking, etc.
Office Systems <i>Person Responsible –Nominee</i>	<ul style="list-style-type: none">• Review processes for using office equipment such as: computer, telephone, voicemail, fax, printer, photocopier, etc.• Review processes for using other university equipment/systems such as: libraries, laboratories, open access computers, etc.• Review computer security, and software usage.• Consider environmental efficiencies (waste, recycling, energy)

<p>Job Specific Training and Development</p> <p><i>Person Responsible – Focal</i></p> <p><i>Points of Each Division</i></p>	<ul style="list-style-type: none"> • Role specific development needs should be reviewed and a suitable program of training should be planned that aligns the individual's skills to their core duties. • Staff with line management responsibilities should be clear as to their duties and attend any relevant training. • Outline the use of annual performance and development reviews as one method for determining ongoing role specific development needs. • Review use of personal development planning tools
<p>Health and Safety</p> <p><i>Person Responsible – Nominee</i></p> <p><i>(Health & Safety Co-ordinator)</i></p>	<ul style="list-style-type: none"> • Physical – fire exits, fire alarms, fire evacuation procedure, fire-training arrangements, manual handling, first-aid arrangements, and other arrangements as required.
<p>Monitoring and Evaluation</p> <p><i>Person Responsible – Focal</i></p> <p><i>Points of Each Division</i></p>	<ul style="list-style-type: none"> • It is important that the Induction programme is monitored and reviewed. • Throughout the period regular review meetings should be held and any adjustments made. • See sample templates to support this process: Checklists, Evaluations.
<p>Probation</p> <p><i>Person Responsible – CEO/ AO</i></p>	<ul style="list-style-type: none"> • For new staff the Probation Policy will apply

APPENDIX 9 - MANDATORY TRAINING

1. Fundamentals of Quality Management System
2. Administrative and Financial regulations
3. The Legislation (NMRA Act) and Implementation
4. Role of NMRA
5. Responsibilities of Divisions of NMRA
6. Basic Procedure of
 - a. Registration of Medicines
 - b. Registration of Medical Devices
 - c. Registration of Borderline Products
 - d. Approval of Clinical trials
 - e. Approval advertisements
 - f. Activities related to quality failures / serious ADR
7. Fundamentals of
 - a. GMP
 - b. GDP
 - c. GPP
 - d. GRP
 - e. GCTP

- APPENDIX 10: Date collection on training received and training requirements – WHO BENCHMARK PROGRAM (PLEASE USE THIS AS A TEMPLATE)

1.NMRA Division:				
2. Focal Point				
3. No of members in the division				
4. Training received (pl hand over a copy of a certificate received after the training program as an evidence)				
	Topic of the training	Received to whom	No of days / hours	Given by
5. Training needs for the future				
	Area or topics	Proposed organization to train		Needed members

Signature

APPENDIX 11 - IN-HOUSE TRAINING FOR ALL THE STAFF –

	Area	Frequency	Resource	Duration	Funds required
A	Fire drill	Annually	External	2 hours	
B	Personnel improvement	Annually	External	8 hours	
B	How to manage time		External		
	How to manage Anger & Stress		External		
	How to solve problems		External		
	How to identify your skills		External		
	Become a Leader		External		
	How to solve problems		External		
C	Computer Skills				
	Computer Basics	Program	SLIDA	5 days	
	Microsoft Office Version Upgrades				
	Word Processing: Microsoft Word				
	Email:				
	Internet Basics				
	Presentations: PowerPoint				
	Spreadsheets: MS Excel				
	Databases: MS Access				
D	Communication skills & Techniques		External	2 days	
	Effective communication				
	Public communication				
	E – Communications				
	Written Communication				
F	Outbound Training / Learning for enhancing individual, team and organizational performance through experiential learning methodology where participants are involved into outbound training activities and outbound training games.				

APPENDIX 12 NMRA STAFF TRAINING – AS APPLIED TO EACH DIVISION

	Title	Description	Target audience	Instructor	hrs	Frequency	Fund
1	Supply system of medicines	Lecture(s)	Non-technical staff, NMRA		2	Once	
2	Difference between CDD Act and the NMRA Act	Lecture	Non-technical staff, NMRA			Once	
2	Quality Management System (QMS) and its importance	Lecture	Non-technical staff, NMRA	**		Once	
3	Sharing knowledge of foreign training gain by the NMRA staff	Individual presentation by the one who got the training	Technical Staff	decided by the relevant presenter			
4	a) Product characteristics and information	Lectures	Tech. staff, NMRA		01	Once	
	b) API Assessment						
	c) Bioequivalence and Bio-waivers				02	Once	
	d) Stability studies				02	Once	
	e) Specifications				02	Once	
	f) Method validation				02	Once	
	g) Batch records				01	Once	
	h) Packaging				01	Once	
	i) Variations				02	Once	

	j) Preparing evaluation reports						
0 5	Good Pharmacy Practices	Seminar	NMRA Staff	02			
0 6	Good Distribution Practices	Seminar					
0 7	GMP Inspection	Seminar	NMRA Staff	10		One per every District per year	
0 7	Good Regulatory Practices	Seminar	NMRA Staff	02		One	
0 8	GMP Inspection	Seminar	NMRA Staff	10		05 events	

TRAINING AND EDUCATION PROGRAM FOR UNIVERSITY STUDENTS – NMRA
Date:

	Topic	period	Trainer	Signature
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		(Hr)		- Trainer
1	Overview of Regulatory Control of NMRA	1		
2	Overview of NMRA Act and Regulations	1		
3	Registration of Medicines	1		
4	Registration of vaccines and biological products	1		
5	Conduction of Clinical Trials	1		
6	Controls on Narcotic medicines	1		
7	Activities related to quality failures	0.5		
8	Safety and efficacy issues of medicines and “Pharmacovigilance”	1		
9	Regulations on Advertisements	0.5		
10	Regulation of Pharmacies & wholesalers	1		
11	GMP Inspections	2		
12	Implementation of GPP and GDP	1		
13	Registration of Medical Devices	1		
14	Registration of Borderline products	1		
14	Registration of Cosmetic products	1		
15	Self-studies by the trainees			
	1. Evaluation of			

	application for registration of Medicines			
	2. Evaluation of application for registration of Medical Devices			
	3. Evaluation of application for registration of Borderline products			
	4. NMRA Law Enforcement activities			
	5. Administrative activities			
1 6	Review of the training			
NMQAL				
1	Overview of Quality Assurance system			
2	Quality Control Activities 1. Chemical Division 2. Microbiological Division 3. Biological Division			
3	Post Marketing Surveillance system			
4	Demonstration of QC activities 1. Chemical Division 2. Microbiological Division 3. Biological Division			
5	Sampling procedure			
6	Laboratory safety			

	guidelines			
	Review of the training			

9. VERSION HISTORY

Organization, Personnel Management and Training

Version	Date Approved	Changes

10. FEEDBACK

10.1 Staff and customers may provide feedback about this document by emailing info@nmra.gov.lk.

11. APPROVAL AND REVIEW DETAILS