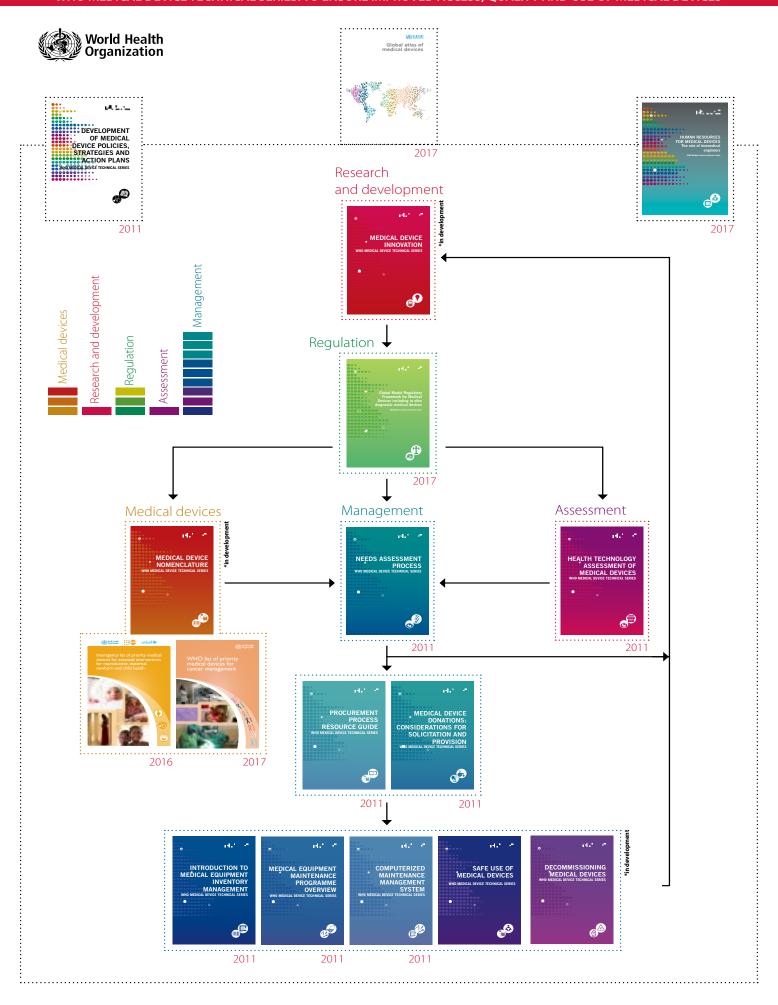


HUMAN RESOURCES FOR MEDICAL DEVICES The role of biomedical engineers

WHO Medical device technical series







HUMAN RESOURCES FOR MEDICAL DEVICES The role of biomedical engineers

WHO Medical device technical series



Human resources for medical devices, the role of biomedical engineers (WHO Medical device technical series)

ISBN 978-92-4-156547-9

© World Health Organization 2017

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. Human resources for medical devices, the role of biomedical engineers. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see http://www.who.int/about/licensing.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters. All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Design & layout: L'IV Com Sàrl, Villars-sous-Yens, Switzerland.

Editorial consultant: Vivien Stone, Etchingham, UK.

Printed by the WHO Document Production Services, Geneva, Switzerland.

Contents

Pr	eface.		5
	Medi	ical device technical series – methodology	6
	Scop	oe	9
	Defin	nitions	10
Ac	know	ledgements	12
۸۵	ronyn	ns and abbreviations	1.4
AU	lonyn	is and appreviations	14
Ex	ecutiv	ve summary	15
Bio	omedi	ical engineers as human resources for health	20
	Resp	oonsibilities and roles	21
		nedical engineering	
	Globa	al Strategy on Human Resources for Health: Workforce 2030	27
1	Glob	al dimensions of biomedical engineering	30
	1.1	Biomedical engineers – global data	30
	1.2	Women in biomedical engineering	
	1.3	Biomedical engineering in international organizations	
	Conc	clusion	37
2	Educ	cation and training	39
	2.1	Defining training and education	39
	2.2	Core curriculum and elective specialization	
		2.2.1 Core curriculum	
	0.0	2.2.2 Elective specialization	
	2.3	Universities – global data	
	2.4	Education and training by region	
		2.4.2 Asia-Pacific	
		2.4.3 Australia and New Zealand.	
		2.4.4 Europe	46
		2.4.5 Latin America	
	0.5	2.4.6 North America (USA and Canada only)	
	2.5	International accreditation agreements	
		Bologna Declaration, 1999	
	2.6	List of educational institutions	
3	Profe	essional associations	54
	3.1	Purpose of professional associations	
	3.2	Global biomedical engineering associations	
		3.2.1 International Union for Physical and Engineering Sciences	
		in Medicine	
		3.2.2 International Federation for Medical and Biological Engineer	ing 56

	3.3 3.4	 3.2.3 Institute of Electrical and Electronics Engineers - Engineering in Medicine and Biology Society Professional biomedical associations – global data Phases of institutional development of a profession 3.4.1 Institutional maturity of biomedical engineering 	. 56 . 59
4	Certif	cation	61
	4.1	Defining certification	
	4.2	International certification of biomedical engineers	
	4.3	Certification by region	. 64
		4.3.1 Certification in Africa	
		4.3.2 Certification in the Americas	
		4.3.3 Certification in Asia	
5	Devel	ppment of medical devices policy	. 73
	5.1	Introduction	. 73
	5.2	International organizations	
		5.2.1 United Nations Population Fund	
		5.2.2 United Nations Office for Project Services5.2.3 United Nations Children's Fund	
		5.2.4 World Health Organization	
	5.3	National organizations	
	5.4	World Health Organization – medical devices	
	5.5	Conclusion	
6	Medi	al device research and innovation	. 80
	6.1	Introduction	
	6.2	The field of medical device innovation	
	6.3	Innovation competencies	
	6.4 6.5	Skills requirements	
	6.6	The innovation process and its increasing scope	
	6.7	Medical device innovation for low-resource settings	
	6.8	Conclusion	
7	Role	f biomedical engineers in the regulation of medical devices	20
•	7.1	Introduction	
	7.1 7.2	Need for biomedical engineers in regulatory affairs	
	7.3	Medical devices regulation – scope and function in different countries.	
	7.4	Professionals in the field of medical devices regulation	
	7.5	Biomedical engineers as regulatory specialists in industry	
	7.6	Professional functions fulfilled by biomedical engineers in the	
		regulatory domain	
		7.6.1 New product planning	
		7.6.2 Research and development	
		7.6.3 Clinical research	
		7.6.4 Quality management systems and manufacturing operations 7.6.5 Marketing and sales	
		7.6.6 Technical writing	
		7.6.7 Health economics and health technology assessment	
		7.6.8 Standards and standardization bodies	

	7.7	Industry and government affairs	. 95
	7.8	Education and experience of industry regulatory affairs	
		professionals	. 95
	7.9	Conclusion	. 96
8	Role	of biomedical engineers in the assessment of medical devices	. 99
	8.1	Introduction	. 99
		8.1.1 From performance to use in health care	101
	8.2	Methods of health technology assessment.	102
	8.3	Different disciplines in health technology assessment	103
	8.4	Core competencies required for health technology assessment	103
		8.4.1 Interdisciplinary teams	103
	8.5	Survey of biomedical engineers involved in health technology	
		assessment	105
	8.6	The developing role of biomedical engineers	107
	8.7	Professional societies and international collaboration in health	
		technology assessment	108
		8.7.1 Health Technology Assessment international	
		8.7.2 International Network of Agencies in HTA	
		8.7.3 EuroScan International Network	
		8.7.4 HTAsiaLink	109
		8.7.5 La Red de Evaluación de Tecnologías Sanitarias de las Américas	
		8.7.6 European Network for HTA8.7.7 Eastern Mediterranean Regional Network in HTA	110
		8.7.8 Health Care Technology Assessment Division (IFMBE)	
	8.8	Conclusion	
9	Role	of biomedical engineers in the management of medical devices	113
	9.1	Introduction	113
	9.2	Biomedical engineering activities through the life cycle of devices	
		and systems	114
		9.2.1 Health technology assessment	
		9.2.2 Procurement	
		9.2.3 Health risk management	
		9.2.4 Health information technology	
		9.2.5 Health technology management.	
		9.2.6 Education and user training9.2.7 Ethics committee	
	9.3	9.2.7 Ethics committee	
	9.5	9.3.1 In-house personnel model	
		9.3.2 Mixed model	
		9.3.3 Third-party multi-vendor service model	
		9.3.4 Biomedical engineering departmental structures within hospitals.	
		9.3.5 Key roles in a biomedical engineering department	121
	9.4	Biomedical engineering around the world	
		9.4.1 Global survey of biomedical engineering	
	9.5	Conclusion	
10	Role (of biomedical engineers in the evolution of health-care systems	127
	10.1	Biomedical engineering for 21st-century health-care systems	
	10.1	Revolutions impacting biomedical engineering	
	10.2	Novoiduono impacime diomicalcai engineemite	14/

	10.3	Other contextual factors driving change in health-care systems					
	10.4	Biomedical engineers work in many sectors					
		10.4.1 Evolution in biomedical engineering career paths					
	10.5	Evolution of modern medical devices					
		10.5.1 Telehealth and telemedicine					
		10.5.2 More sophisticated organizational and IT requirements	132				
	10.6	Mission critical: Systems engineering and systems of systems					
		engineering	132				
	10.7	Elements of an ideal, integrated health and information technology					
		system	133				
	10.8	Establishing a comprehensive biomedical engineering value					
		proposition	134				
	10.9	Build competencies in strategic, clinical and operational domains					
	10.10	Dimensions of career development in biomedical engineering					
		10.10.1 A biomedical engineer's career anchor considerations	138				
		10.10.2 Biomedical engineering career stages	138				
		10.10.3 Key emerging biomedical engineering competency opportunities					
		Training topics	140				
		Conclusion					
	10.13	Further reading	141				
11	Concl	usions and recommendations	144				
	11.1	Future role of biomedical engineers in low- and middle-income					
		countries	145				
	11.2	Reclassification of biomedical engineers and technicians					
	11.3	Final statement					
		Biomedical engineers by country and relevant demographic	1 40				
ma	icators	i	149				
Δnı	1ex 2 F	ducational institutions with biomedical engineering programmes	154				
- AIII	.5x 2 L	management into the control of the c	107				
Annex 3 National and international professional biomedical engineering							
ass	ociatio	ons	207				
Annex 4 Survey respondents							

预览已结束, 完整报告链接和二维码如下:

https://www.yunbaogao.cn/report/index/report?reportId=5_26296



