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A GUIDE FOR THE QUALITY ASSURANCE OF SINGLE USE INJECTION EQUIPMENT

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The author would like to thank the regulatory authorities of the founding members of the Global Harmonization Task Force (GHTF) and the International Association of Safe Injection Technology (IASIT) for their contributions in developing this guide.

1 OBJECTIVE

This guide is intended to aid procurement officers who wish to purchase single use injection equipment on a national market or an international market. It is constructed around three components. First, it provides an overview of the relevant standards available and the current regulatory requirements. Second, it recommends a checklist of essential information that must be obtained from potential suppliers about the proposed products. Third, it provides a flow-chart to check information and guide decision-making in terms of product quality.

This guide focuses on sterile hypodermic syringes and needles for single use. Devices included are:

- Conventional single use syringes and needles;
- Single use syringes and needles with features to guard against needle-stick;
- Auto-disable single use syringes and needles.

2 BACKGROUND INFORMATION

The means to ensure the safety and performance of injection equipment include standards and national regulations. In general, standards are voluntary while regulations are mandatory. Regulations, however, can make certain standards mandatory. In addition, purchasers may also have their own specifications that a product must fulfill (e.g., a purchaser may only want syringes of a certain volume or a certain feature such as auto-disable).

There are different types of standards and they cover a wide range (e.g., private, public, organizational, regional, national and international standards). As global health care products, single use injection equipment normally follows international standards. In this guide only the product standards and the quality system standards will be referred to. Product standards describe characteristics for general safety and performance of the product (Table 1). Quality system standards (see Table 2) provide the essential elements and requirements that a manufacturer should have in place to ensure that the quality of products manufactured is consistent.

The government authorities of the country in which a product is manufactured or imported usually enforce regulations. However, many countries do not yet have regulations for medical devices, although some are in the process of establishing such regulations. While this is encouraging, a proliferation of different national regulations can hinder access to technology and thus should be avoided. The Global Harmonization Task Force (GHTF) (www.ghtf.org) aims at harmonizing regulatory requirements and practices based upon essential principles and common criteria. GHTF recommendations provide a useful reference to assist countries in the development of medical device regulations.

This guide is based upon the regulatory requirements for single use syringes/needles of the five founding members of the GHTF. These are Australia, Canada, the European Union, Japan and the United States. Although many countries that are capable of manufacturing single use syringes have no established regulatory systems, it is anticipated that the global market will lead them to follow the recommendations of the GHTF.

2.1 Standards

2.1.1 Product standards

Table 1 lists the current international standards governing injection equipment that are recognized by Australia, Canada, the European Union, Japan and the United States of America, the five founding members of the GHTF.

Table 1: International standards for single use syringes and needles *

1	ISO 7864	Sterile hypodermic needles for single use
2	ISO 7886-1*	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
3	ISO 7886-2	Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps
4	ISO 8537	Sterile single use syringes, with or without needle, for insulin

* Standards for auto-disable syringes (ISO 7886-3 for fixed dose immunization and ISO 7886-4 for general purpose) are being developed and should be available soon.

2.1.2 Additional specifications

In addition to product standards, purchasers may specify the characteristics of the product they want to purchase through other procurement specifications (e.g., volume, type of syringe, safety devices). WHO procurement specifications for auto-disable (AD) syringes for immunization (WHO/EPI/LHIS/97.11) and for general purpose (WHO/BCT/02.12) constitute an example. While the standard for auto-disable syringes for fixed dose immunization (ISO 7886-3) is being developed, WHO specifies the technical characteristics of the auto-disable syringes that should be purchased by UNICEF for use in immunization programs worldwide.

2.1.3 Quality system standards

Quality systems are defined as the organizational structure, responsibilities, procedures, processes and resources needed to implement quality management (see Section 2.2.2). The quality system standards used by the five founding members of GHTF are listed in Table 2.

Table 2: Quality system standards of the five founding members of the GHTF

Country	Quality system standards
Australia	ISO13485 or EN46001, ISO13488 or EN46002
Canada	ISO13485, ISO13488
European Union	EN46001, EN46002, ISO13485, ISO13488
Japan	GMP (QS Standard for medical devices #1128)
United States	QS (21 CFR part 820)

* Standards for auto-disable syringes (ISO 7886-3 for fixed dose immunization and ISO 7886-4 for general purpose) are being developed and should be available soon.

Note: EN46001 and EN46002 will be phased out by the end of March 2004

2.2 Regulatory requirements.

2.2.1 Product safety and performance

All medical devices (including injection equipment) must comply with the essential principles of safety and performance in design and construction recommended by the GHTF (ref. GHTF document SG1-N02R5)[*]. The GHTF recommends a risk management approach in medical device regulations. Medical devices are classified from the lowest risk, class I, to the highest risk, class III or IV (ref. GHTF document SG1-N015R14). The higher the risk –class, the more regulatory scrutiny there is before a product is placed on the market. The GHTF founding members classify injection syringes and needles as class II products (Appendix B).

2.2.1.1 Conformity with product standards

Conformity with international standards (Table 1) is voluntary for partial fulfillment of the essential principles of safety and performance. Manufacturers, however, can choose other means to demonstrate fulfillment of regulatory requirements. Nevertheless, the majority of manufacturers follow available international standards as a convenient and effective way to comply with regulatory requirements.

2.2.2 Consistency in product quality

Consistency in the quality of the product is ensured by mandating that the manufacturing processes meet quality system standards or "Good Manufacturing Practices". Quality systems are audited by the government or third-party agencies depending on the country. Since most medium to low risk medical devices are relatively simple in design, once the design has been validated to demonstrate fulfillment of regulatory requirements for safety and performance, quality systems in manufacturing become the principal safeguard for consistency in product quality.

2.2.3 Packaging and labeling of products

Adequate packaging and labeling are also regulatory requirements (ref: GHTF document SG1-N009R6). In general, for syringes and needles, the packaging must retain the sterility of the content. Labeling serves to communicate safety and performance related information to users and patients as well as to identify individual devices. Specific packaging and labelling recommendations are given in the product standards listed in Table 1.

[*] GHTF documents can be obtained free of charge from www.ghtf.org

2.3 Marketing clearances

The marketing clearances for the five founding members of the GHTF are listed in Table 3. They signify product compliance with regulatory requirements.

Table 3: Marketing clearances by regulatory authorities

Regulatory authority	Australia (new legislation)	Canada	European Union	Japan	United States
Marketing clearance	GMPALS License or CE Mark	Device license	CE mark *	Device license	510k device letter
Web site checking of marketing clearance †	Awaiting	Yes	Awaiting	Yes ‡	Yes

In summary, for single use syringes and needles, the regulations in these countries ensure that the general requirements for safety and performance are met, that the quality systems for manufacturing are followed, that the packaging is secure and that the labeling is clear. They do not, however, address any special needs for individual device applications. For example, at present, the standard ISO7886-1 commonly adopted by manufacturers covers a wide range of single use syringes of different capacities and needle gauges as well as a guard against needle-stick or auto-disable after use. As certain special needs become more common, the development of international standards follows. ISO 7886-3 (auto-disable syringes for fixed dose immunization) and ISO 7886-4 (auto-disable syringes for general purpose) are being developed.

3 RECOMMENDATIONS FOR PURCHASING SPECIFICATIONS

Calls for tender or purchase orders should specify (1) the product standards that are required,(2) other procurement specifications that the purchaser wishes to apply, (3) the quality system standards that are required and (4) essential information required for product selection.

3.1 Product standards

It is recommended to ask for products that conform with the applicable ISO standards for products listed on Table 1.

* The CE mark is not a permit issued by an external authority but a declaration by the manufacturer of product conformity with regulatory requirements. It is important to verify that an accredited Notified Body has done conformity assessment and that the identification number is on the CE marking.
† See appendix A.
‡ Available in Japanese language only.

3.2 Additional specifications

Special features of the required products must be clearly stated in the purchasing specifications. Make sure that any such additional specifications do not conflict with international standards.

3.3 Quality system standards

It is recommended to ask for products that are manufactured in conformity with one of the quality system standards listed on Table 2 that are required by the GHTF founding members.

It should be noted that the ISO13485 and ISO13488 standards have recently been specified by regulatory authorities while the ISO9001 and ISO9002 standards have been in common use worldwide. To allow a phase-in period (till July 2004), manufacturers registered with ISO9001, ISO9002, ISO9001:2000 should be accepted as having quality systems in place. However, preference should be given to products from manufacturers registered with ISO13485 / ISO13488 if other value indicators are equal.

The ISO9001 and ISO9002 standards are for general application for products or services. The ISO13485 and ISO13488 standards are for the medical device industry. ISO13485 includes all the elements of ISO9001 plus a minimum set of supplementary requirements for the quality assurance of medical device manufacturing (see Appendix C). The same relationship exists for ISO13488 and ISO9002. ISO13488 is equivalent to ISO13485 but without the design control requirements.

3.4 Essential information required for product selection

It is recommended to ask the potential suppliers to complete the checklist for product information provided in Table 4 by following the accompanying instructions.

4 RECOMMENDATIONS FOR PRODUCT SELECTION

It is recommended to use the flow-chart provided in Figure 1 to qualify proposed products for selection. Two categories of qualified products are:

1. Track 1: Clearance by a founding member of the GHTF

Products that comply with regulatory requirements of at least one of the founding members of the GHTF and that also satisfy other procurement specifications.

2. Track 2: Clearance by alternative means

Products that are manufactured in conformity with acceptable quality system standards and specified product standards and that also satisfy additional specifications.

Comparison of products

All factors including price, post-market evaluation or any special features must be taken into consideration. Technical expertise is required in evaluating incident reports; it is not the number of reports that is the indicator of quality but the seriousness of the incidents that counts.

Table 4: Checklist of product information

		Information item	Details				
		Item short description					
1	☐	Brand name				**Remarks**	
			Status* and Name	**Address**	**Phone and Fax**	**Contact person for quality assurance**	**Web-site, e-mail**
2	☐	Vendor					
3	☐	Manufacturer					
	☐	Manufacturing site (Origin of goods)					
4	☐	Parent company (if any)					
5	☐	Compliance with regulations	**Regulatory authority (check all applicable)**	**Number (provide number)**		**Device name as submitted to authorities**	
			❑ Australia	License number:			
			❑ Canada	License number:			
			❑ European Union	CE mark number:			
			❑ Japan	License number:			
			❑ United States	510(k) number:			
			❑ Other, specify:				
6	☐	Conformity with quality system standards	**Standards used (check applicable)**	**Assessment body† (name, country), (attached a copy of the certificate)**		**Last audit date**	**Expiration date**
			❑ ISO13485 /ISO13488				
			❑ EN46001 / EN46002				
			❑ Japan QS Standard #1128				
			❑ United States QS (21 CFR part 820)				
			❑ ISO9001 /ISO9002				
			❑ Other, specify: (e.g. ISO9001:2000)				
7	☐	Conformity with product standards	**Standards used (check applicable)**	**Test laboratory‡ (name, country) (attached a copy of the certificate)**		**Laboratory accreditation body**	
			❑ ISO 7864 for needles				
			❑ ISO 7886-1 syringes for single use				
			❑ ISO 7886-2 syringes for power-driven pumps				
			❑ ISO 8537 for insulin				
			❑ Other standards, specify:				
8	☐	Post-market surveillance reports	❑ Yes (**check applicable.** If yes, please provide all reports including sources. Use additional pages if necessary) ❑ No				
9	☐	Other evaluation reports	❑ Yes (**check applicable.** If yes, please provide all reports including sources. Use additional pages if necessary) ❑ No				

* Status: please provide the status as a vendor such as wholesaler, manufacturer, distributor, etc.
† E.g., Notified bodies in the European Union; Quality Systems Registrars in North America.
‡ Product testing must include sterility, packaging and labeling requirements.

Instructions for completing Table 4 : Checklist of product information

All potential suppliers (or original manufacturers) please fill in items 1,2,3,4,8,9. In addition,

- If a regulatory authority has cleared the device, fill in item 5.
- If a regulatory authority of the GHTF founding members has not cleared the device, fill in items 6 and 7.

Item 1: Please provide the brand name that is used on the market. If there is more than one name, please provide all names.

Item 2 and item 3: The vendor may also be the manufacturer. But if the addresses are different, please provide all information.

Item 4: If the manufacturer is a subsidiary of a parent company or is contracted from another company, please supply the necessary information. A parent company may be located locally or in another country.

Item 5: If there is more that one regulatory authority that has cleared the product, please check all applicable authorities and provide all clearance numbers with the corresponding device names as they were submitted to the regulatory authorities. The device name submitted to the regulatory authorities, which may be different from the brand name, is necessary for verification of marketing clearance by the relevant regulatory authorities.

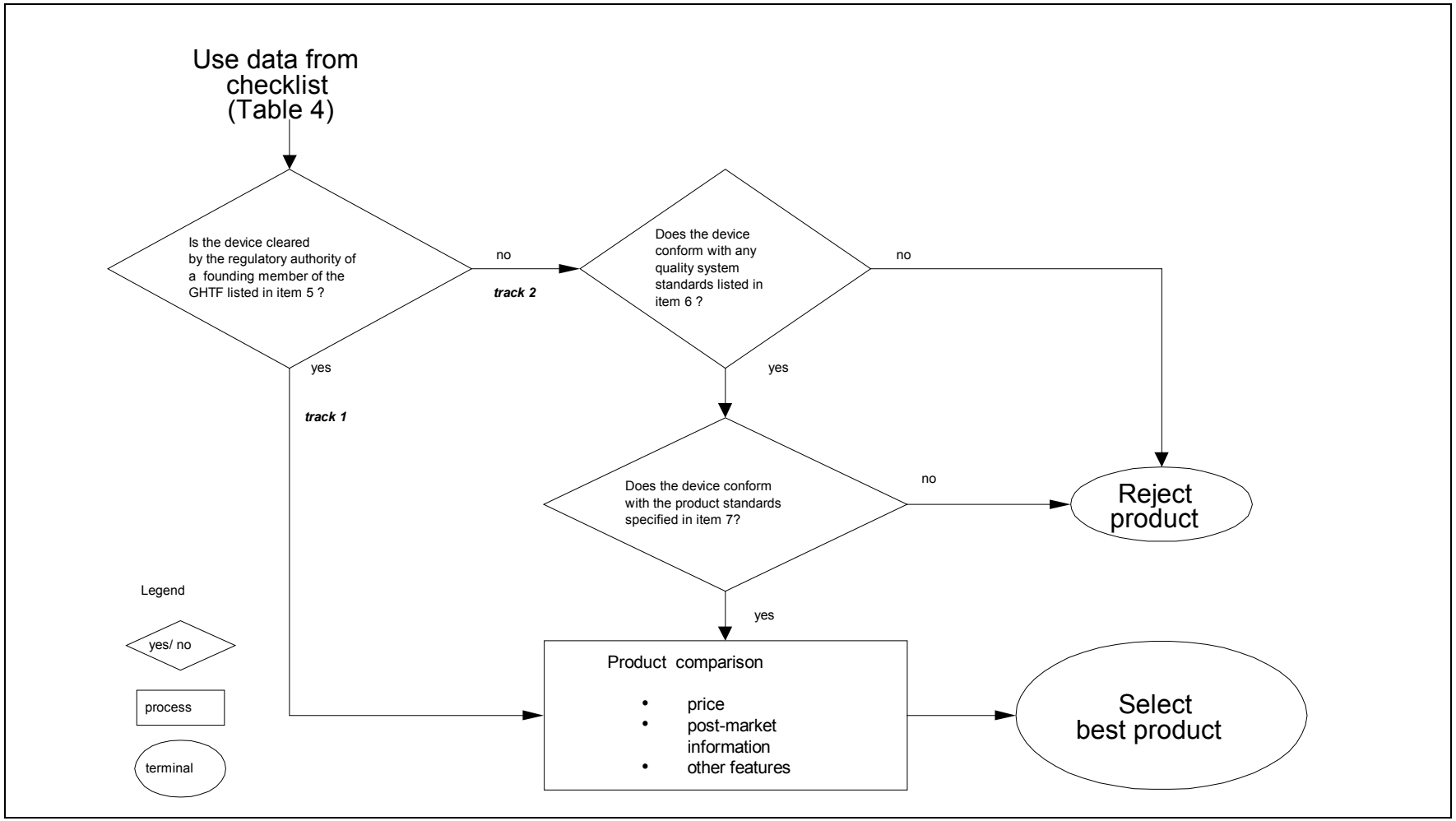
Item 6: Please confirm the applicable standard. Quality system assessment must include: (1) whether the proposed product is manufactured under the quality system audited; (2) whether the appropriate international (ISO) standards for sterilization and packaging are used for Section 4.9 “process control”, (3) last audit date and expiration date of certificate. Maximum audit period must not exceed 12 months. Note that devices that are manufactured in conformity with ISO13485/88 will be given preference to those manufactured with ISO9001/02 or ISO 9001:2000.

Item 7: Please check all applicable standards with the corresponding test laboratories. Product testing must include sterility, packaging and labeling requirements. Indicate the accreditation status of the laboratories.

Item 8: Please provide all post-market surveillance reports by regulatory authorities, users or other parties and specify the sources.

Item 9: If available, provide any other third party evaluation reports.

Figure 1 – Flow chart (decision tree) for product selection



Instructions for using the flow chart for product selection (Figure 1)

Please make sure the checklist (Table 4) is correctly completed. Follow the flow chart (Figure 1) for product selection.

Track 1. If there are no applicable local national regulations, and if the proposed product has marketing clearance from one or more of the five GHTF listed authorities (item 5), this product can be accepted as a candidate for product selection. You may be able to verify the regulatory clearance on the Internet, if available. (See Table 3 and Appendix A)

Track 2. If the proposed product has not been submitted to any of the five listed authorities, then it is necessary to assure that:

1. the manufacturer has a quality system in place (any one of the systems listed under item 6 is acceptable),
2. the proposed product conforms with specified product standards (item 7) and all additional specifications. You may verify the accreditation status of the test laboratory by following the information given by the International Laboratory Accreditation Cooperation (ILAC) (see Appendix A).

If both quality system standards and product standards are satisfactory, the proposed product can be accepted as a candidate for product selection.

If the proposed product is manufactured with an acceptable quality system, but either the conformity of the proposed goods with specified product standards or any additional specifications have not been certified by an accredited laboratory of any founding member of the GHTF, an option is to submit the proposed product to the Force Institute for testing. The expense for this testing will be charged to the potential supplier. If the proposed product passes the laboratory test, then it can be accepted as a candidate for product selection.

Note: The ISO9001 and ISO9002 standards are for general application for products or services. The ISO13485 and ISO13488 standards are for the medical device industry. ISO13485 includes all the elements of ISO9001 plus a minimum set of supplementary requirements for the quality assurance of medical device manufacturing (see Appendix C). The same relationship exists for ISO13488 and ISO9002. ISO13488 is equivalent to ISO13485 but without the design control requirements.

The ISO13485 and ISO13488 standards have recently been specified by regulatory authorities while the ISO9001 and ISO9002 standards have been in common use worldwide. To allow a phase-in period (till July 2004), manufacturers registered with ISO9001, ISO9002, ISO9001:2000 should be accepted as having quality systems in place. However, preference should be given to products from manufacturers registered with ISO13485 / ISO13488 if other value indicators are equal.

REFERENCES

1. Injection safety, report by the Secretariat. WHO Executive Board 107 session. EB107/23, 5 December 2000.
2. WHO/UNCEF/UNFPA joint statement on the use of auto-disable syringes in immunization services. WHO/V&B/99.25.
3. WHO specifications: 0.5 ml auto-disable syringe. Specification reference E8/DS.1
4. WHO specifications: 0.05 ml auto-disable syringe. Specification reference E8/DS.2
5. A guide for the development of medical device regulations: Pan American Health Organization 2002.
6. Guidelines for Health Care Equipment Donation, 4th Draft, World Health Organization, WHO/ARA/97.3
7. WHO Aide-Memoire Series: Safe Medical Devices; Injection Safety; Blood Safety. http://whqlibdoc.who.int/aide-memoire.

APPENDIX A VERIFYING REGULATORY COMPLIANCE

Australia license listing. Currently not available on the Internet.

Mailing address: Conformity Assessment Branch
Therapeutic Goods Administration
PO Box 100, Woden, ACT, 2609, Australia

Canada license listing. Open the Web page at address:
http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/guides/meddev/lic020103_e.pdf
Download **Acrobat Reader** if you do not already have it in the computer.
On the tool bar, click on the "Find" icon (binocular) to verify the device listing. In order of speed, the following keywords can be use for the search:

- Device License Number
- Registered device name
- Company name
- Use words such as "syringe", "single use"…The word must be part of the registered device name

N.B. (1) the search starts from current page and stops at first item that matches the entire word or number being searched. For example, if you start to search the Device License Number 4243 at the beginning of the database, it will stop at 14243 if 14243 is listed before 4243. At this point, you have to click "Find again" to continue the search for 4243 until the end of the database. (2) If you start the search at a current page that comes after the target is listed, it will arrive at the end of database and tell you that the device is not found. Then you have to start search from the beginning page of the database.

Only license number, risk class, device name, registering manufacturer's name are provided; other information about the device is currently not available from the Web.

CE Marks. Currently not available on the Internet. Please check again with the European Community if any progress has been made.

Japan license. The Japan Association for the Advancement of Medical Equipment operates a website (http://www.jamme.or.jp) providing services for searching approved medical device licenses. This service, however, can only be assessed through members paying annual fees.

FDA device listing. Open the Web page at address:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
A search table will appear. Enter official device name or 510k number, and then clicking on the search button will reveal whether the device is listed.

Alternatively, enter the parent company name, and then clicking on search will result in a listing of all 510k-cleared products of the company. FDA listing will provide details about the company, and in some cases statements about the products.

Post-market vigilance information

Australia Internet site: www.health.gov.au/tga. Click on the “recall” button.

United Kingdom Internet site: www.medical-devices.gov.uk Click on the “incident reports” button.

United States FDA Internet sites:
Manufacturer and User Facility Device Experience Database (MAUDE) represents reports of adverse events involving medical devices. The data consists of all voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.

Open the web page at address
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm
A search table will appear. Enter official device name or 510k number, and then click on the search button will confirm whether the device has any post-market information.

Medical Device Reporting Database (MDR) allows you to search the database of the Center for Devices and Radiological Health (CDRH) for information on medical devices which may have malfunctioned or caused a death or serious injury during the years 1992 through 1996.

Open the web page at address
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmdr/search.CFM
A search table will appear. Enter official device name or parent company name, and then click on search button will confirm whether the device has any mandatory post-market Medical Device Reports.

ECRI (the Emergency Care Research Institute) also has a database on medical device alerts (HDA). This service, however, can only be assessed through members paying an annual fee. The website is www.ecri.org

ILAC International Laboratory Accreditation Cooperation

Laboratory Accreditation provides formal recognition to competent laboratories. An international guide, called ISO/IEC Guide 25, describes the basis for the accreditation of a country's testing and calibration laboratories. Adoption of this international guide has helped countries adopt a uniform approach to determining laboratory competence.

To find accredited laboratories around the world, open the web page http://www.ilac.org/
Click “the “Directory” button will result in a world map and instructions to find members in different regions and their addresses or websites for communications. Enquiries can then be made to regional authorities for further information about accredited laboratories.

APPENDIX B SUMMARY OF REGULATORY REQUIREMENTS

Table 5: Requirements in the five founding members of the GHTF

	Australia Under the proposed new legislation	Canada	European Union	Japan	United States
Regulation	Yes	Yes	Yes	Yes	Yes
Device Class	IIa	II	IIa	II	II special control
Safety and effectiveness	Yes	Yes	Yes	Yes	Yes
Recognized device & test standards *	5 standards	Manufacture declaration	5 standards	1 standard	9 standards
Labeling	yes	Yes	Yes	Yes	Yes
Quality systems for manufacturing	ISO 13488 or ISO 13485	ISO13488	EN46002	GMP based on ISO13485	QS (21CFR part 820)
Quality systems audit	Government and 3rd Party	3rd party	3rd party	Government	Government
Pre-market review or conformity assessment	Review by TGA	Vendor attestation of compliance to Health Canada	Conformity assessment by a Notified Body. Special requirements depend on individual state	Review by MHLW (Ministry of Health & Labor Welfare)	510k review by FDA or accredited person †
Marketing permit	GMPALS License or CE Mark	Device license	CE mark	Device license	510k device letter
Website verification of marketing permission	Not presently	Yes	Not presently	Yes, but Japanese language only	yes

* Conformity with recognized standards are voluntary. Manufacturers can choose other means to satisfy safety and effectiveness requirements.

† A person or an organization in any country may apply for accreditation by FDA. This accredited person can do the 510K reviews but not the quality system inspection. At present, quality systems audits must be done by FDA.

Table 6: Australia, Canada and the European Union recognized standards

	Standards	Title
1	ISO 6009	Hypodermic needles for single use - Color coding for identification
2	ISO 7864	Sterile hypodermic needles for single use
3	ISO 7886-1	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
4	ISO 7886-2	Sterile hypodermic syringes for single use - Part 2: Syringes for use with power-driven syringe pumps
5	ISO 8537	Sterile single use syringes, with or without needle, for insulin

Table 7: FDA recognized standards

	Standards	Title
1	ISO 6009	Hypodermic needles for single use - Color coding for identification
2	ISO 7864	Sterile hypodermic needles for single use
3	ISO 7886-1	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
4	ISO 8537	Sterile single use syringes, with or without needle, for insulin
5	ISO 594	Conical fittings with Luer taper
6	ISO 9626	Stainless steel needles
7	ANSI/HIMA	Luer taper
8	Military Std	MIL-S-36157 or later edition
9	ASTM	for stainless steel tubing testing

Table 8: Japan recognized standards

	Standards	Title
1	Notification No. 1079 of Japanese MHLW	Standard for Sterile Hypodermic Syringe

Note:The above standard partly refers to following ISO and Japanese standards.

- ISO 7886-1 Sterile hypodermic syringes for single use - Part 1: Syringes or manual use
- ISO 594 Conical fittings with Luer taper
- The Standard for Silicone Oil as A Lubricant for Use in Medical Devices (I) (Notification No.327 of Japanese MHLW)
- Japanese Pharmacopoeia
- Guidelines for basic biological tests of medical materials and devices based on ISO 10993-1 (Notification No.99 of Japanese MHLW)
- Standard for Sterilization Validation based on ISO and EN (Notification No.1 of Japanese MHLW)

APPENDIX C ISO9001:1994 AND ISO13485:1996 RELATIONSHIP

Quality System requirements are specified in the standard ISO9001 for the twenty main elements (4.1 to 4.20) listed under the ISO9001 column. Additional requirements for medical devices are listed under the ISO13485 column. An updated stand-alone ISO13485 is being developed to be the sole international quality system standard for regulatory purposes with medical devices.

For sterile products, the conformity with applicable international (ISO) standards on sterilization and packaging is the audit responsibility under 4.9 “process control”.

Table 9: ISO 9001 and ISO 13485 relationship (main sections only)

	ISO 9001:1994	ISO 13485:1996
3	Definitions of ISO 8402 + 2 additional ones	Same as ISO 9001 + 8 additional definitions
4.1	Management Responsibility	Same as ISO 9001
4.2	Quality System	4.2.1 Establish and document specified requirements 4.2.3 Specification and quality system requirements for each model
4.3	Contract Review	Same as ISO 9001
4.4	Design Control	4.4.1 Evaluate needs for risk analysis and maintain records 4.4.8 Clinical evaluation in design validation
4.5	Document and data control	4.5.2 Obsolete documents retained for lifetime of device
4.6	Purchasing	4.6.3 Traceability in 4.8 applies
4.7	Control of Customer Supply Product	Same as ISO 9001
4.8	Production identification and traceability	4.8 Procedures for returned devices and for traceability to facilitate corrective and preventive action
4.9	Process control	4.9 Personnel, environment, cleanliness, maintenance, installation and software-related requirements
4.10	Inspection and testing	4.10.5 Identify personnel
4.11	Control of Inspection, Measuring and Test Equipment	Same as ISO 9001
4.12	Inspection and Test Status	Same as ISO 9001
4.13	Control of non-conforming product	4.13.2 Regulatory requirements have precedence
4.14	Corrective and preventive action	4.14.1 Complaints and feedback system regarding problem investigation, advisory notice, etc.
4.15	Handling, storage, packaging, preservation and delivery	4.15.1 Control for product with limited shelf life 4.15.4 Identify personnel performing labeling 4.15.6 Identify shipping package consignee
4.16	Quality record	4.16 Retention of records, for lifetime of product, but not less than 2 years
4.17	Internal Quality Audit	Same as ISO 9001
4.18	Training	Same as ISO 9001
4.19	Servicing	Same as ISO 9001
4.20	Statistical Techniques	Same as ISO 9001

APPENDIX D RESOURCES

1. WHO Product Information Sheets 2000 Edition.
   Section 8 Equipment for administration of vaccine and micronutrients.
   WHO/V&B/00.13 ORIGINAL: ENGLISH DISTR.: GENERAL (PIS)

2. WHO injection safety toolbox at www.who.int/injection_safety

3. Safe Injection Manual. PATH Technologies for Immunization.
   http://www.path.org/technos/ht_safe_injection_manual.htm

4. Single use medical products price guide: ECRI http://www.ecri.org

5. Weekly e-mail newsletter of the Safe Injection Global Network (SIGN) [sign@who.int]

6. International Association of Safe Injection Technology: http://www.iasit.org

7. The Global Alliance for Vaccines and Immunization. http://www.vaccinealliance.org

APPENDIX E FEEDBACK QUESTIONNAIRE

Your comments and suggestions will be greatly appreciated. They may be sent to the World Health Organization, Department of Blood Safety and Clinical Technology, Avenue Appia 20, 1211 Geneva 27, Switzerland. Fax +41 22 791 4836. E-mail: sign@who.ch.

1. Is this guide easy to understand?

Very dissatisfied	Dissatisfied	Neutral	Satisfied	Very satisfied
1	2	3	4	5

Specific comments

2. Did you identify any imprecision and / or inaccuracies?

3. Has this guide achieved its objectives? (Does this guide provide sufficient guidance to a non-specialized purchasing agent to make decision about the quality of proposed products)?

4. What other information do you think should be included in this guide?

5. Do you use single use injection syringes?

6. In what way are you involved with purchasing single use injection syringes?

7. What is the percentage (%) of injection equipment currently accepted that would now be rejected following the guide recommendations?

8. Please give an overall rating on this guide.

Very dissatisfied	Dissatisfied	Neutral	Satisfied	Very satisfied
1	2	3	4	5