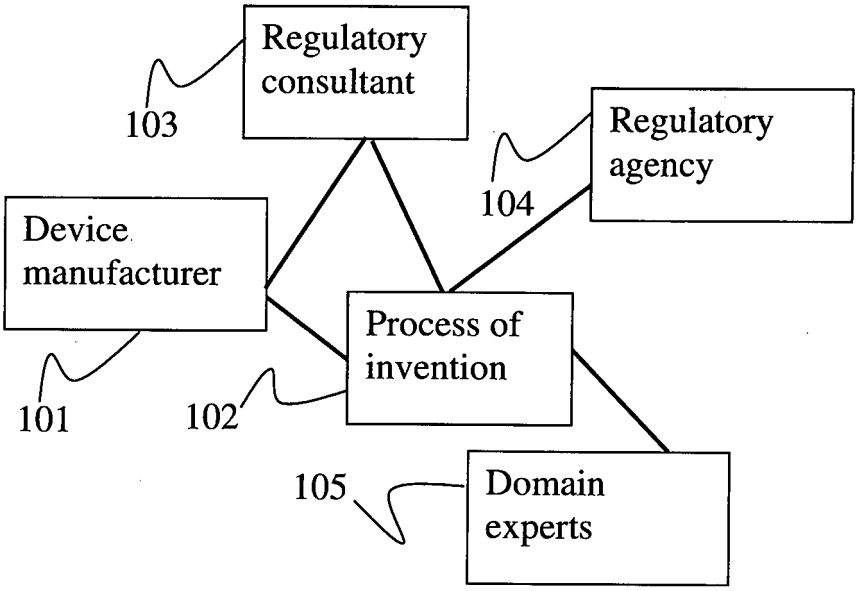
Regulatory consultant
103
Regulatory agency
104
Device manufacturer
Process of invention
101
102
105
Domain experts

Fig. 1

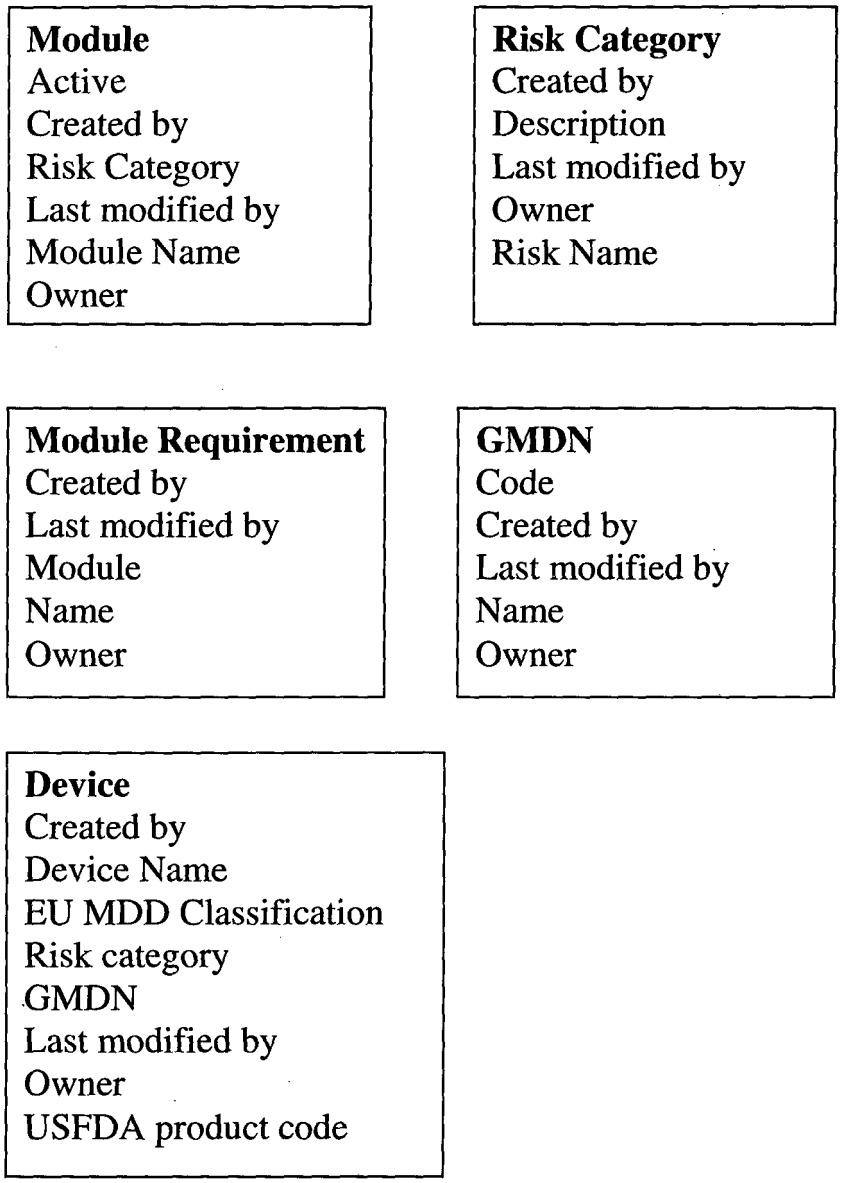
Module
Active
Created by
Risk Category
Last modified by
Module Name
Owner
Risk Category
Created by
Description
Last modified by
Owner
Risk Name
Module Requirement
Created by
Last modified by
Module
Name
Owner
GMDN
Code
Created by
Last modified by
Name
Owner
Device
Created by
Device Name
EU MDD Classification
Risk category
GMDN
Last modified by
Owner
USFDA product code

Fig. 2

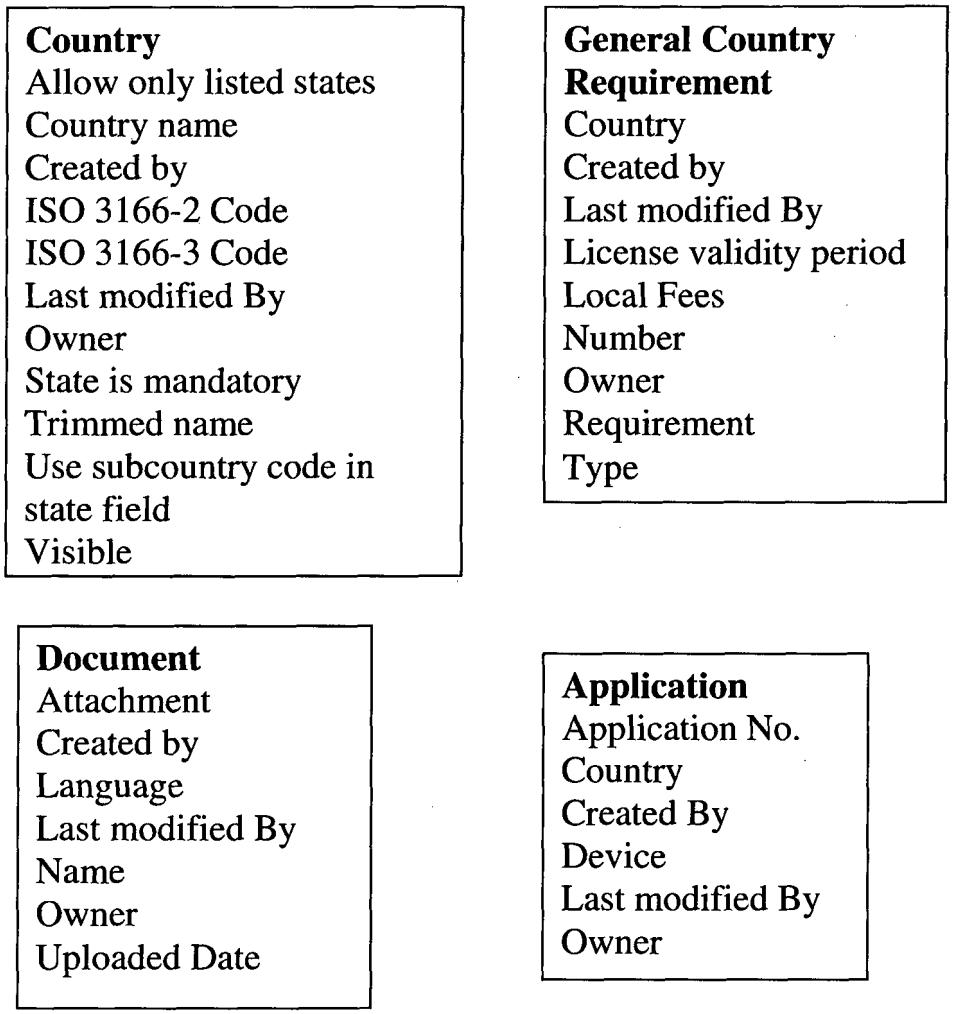
Country
Allow only listed states
Country name
Created by
ISO 3166-2 Code
ISO 3166-3 Code
Last modified By
Owner
State is mandatory
Trimmed name
Use subcountry code in state field
Visible
General Country Requirement
Country
Created by
Last modified By
License validity period
Local Fees
Number
Owner
Requirement
Type
Document
Attachment
Created by
Language
Last modified By
Name
Owner
Uploaded Date
Application
Application No.
Country
Created By
Device
Last modified By
Owner

Fig. 3

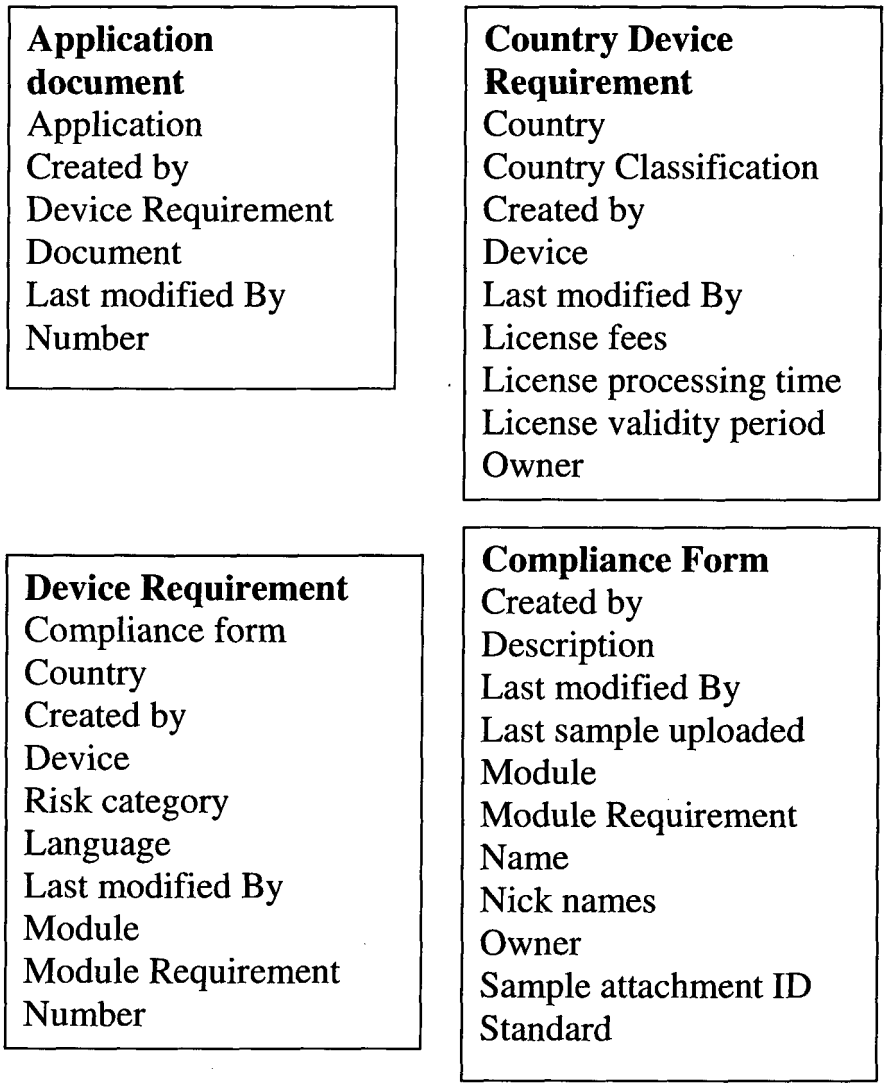
Application document
Application
Created by
Device Requirement Document
Last modified By
Number
Country Device Requirement
Country
Country Classification
Created by
Device
Last modified By
License fees
License processing time
License validity period
Owner
Device Requirement
Compliance form
Country
Created by
Device
Risk category
Language
Last modified By
Module
Module Requirement
Number
Compliance Form
Created by
Description
Last modified By
Last sample uploaded
Module
Module Requirement
Name
Nick names
Owner
Sample attachment ID
Standard

Fig. 4

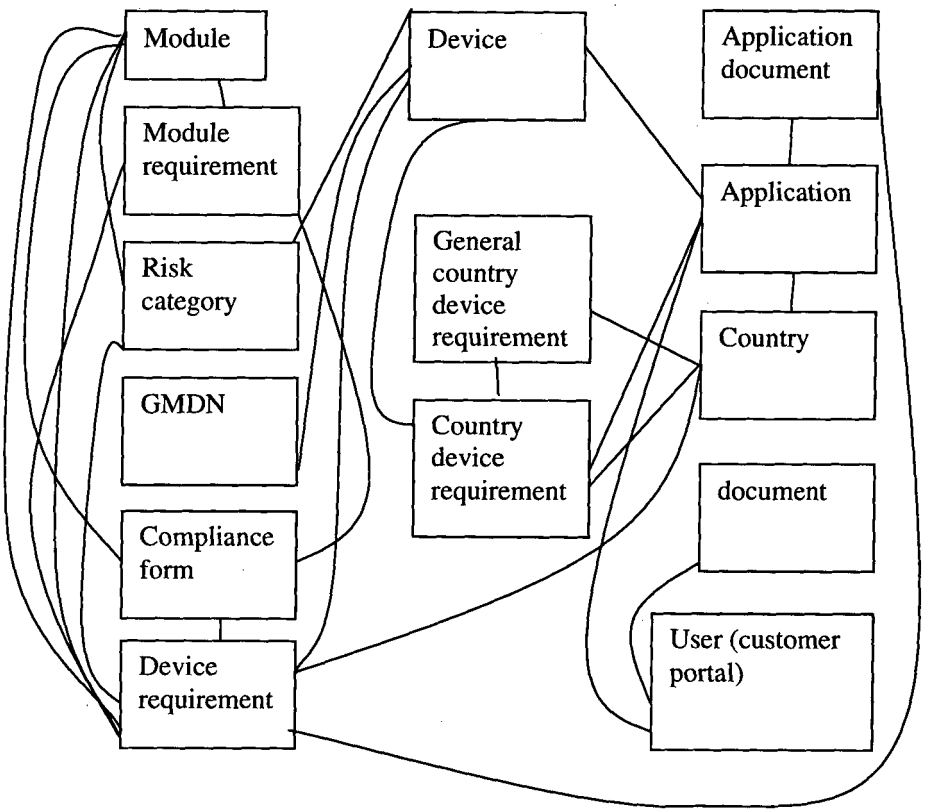
Module
Module requirement
Risk category
GMDN
Compliance form
Device requirement
Device
General country device requirement
Country device requirement
Application document
Application
Country
document
User (customer portal)

Fig. 5

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s
http://www.fda.gov/cdrh/ode/guidance/1567.html

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html	✓ Sec. 1		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf	✓ Sec. 2		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓ Sec. 3		
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D www.fda.gov/cdrh/devadvice/314312.html#link_6	✓ Sec. 4		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E www.fda.gov/cdrh/devadvice/314312.html#link_7	✓ Sec. 5		
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G www.fda.gov/cdrh/devadvice/314312.html#link_9	✓ Sec. 6		
Class III Summary and Certification	Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html			✓
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html.			✓
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html. FDA Standards program www.fda.gov/cdrh/stdsprog.html. Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/reqrecstand.html	✓ Sec. 7		
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓ Sec. 8		

Fig. 6

Title	Related Information	Present	Inadequate	N/A
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓ Sec. 9		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), www.fda.gov/cdrh/k863.html	✓ Sec. 9 Sec. 15		
Proposed Labeling	Device Advice " Content of a 510(k)" Section H www.fda.gov/cdrh/devadvice/314312.html#link_10	✓ Sec. 11		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) www.fda.gov/cdrh/ode/guidance/361.html For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices www.fda.gov/cdrh/ode/guidance/1216.html	✓ Sec. 12		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" www.fda.gov/cdrh/g951.html	✓ Sec. 13		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices www.fda.gov/cdrh/ode/software.html			✓
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program www.fda.gov/cdrh/emc See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)			✓
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓ Sec. 14		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			✓
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf			✓
Kit Certification	Device Advice http://www.fda.gov/cdrh/devadvice/314c.html			✓

Fig. 7

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Fig. 8

⚠ WARNING. If an implant is placed under weight that exceeds its functional capacity, excessive bone loss and/or structural sagging of the implant may occur. Different physiological and anatomical conditions could have an effect on the effectiveness of implant therapy, in particular, the following: inadequate bone quality and quantity, poor or absent oral hygiene monitoring, presence of blood disorders, and non-controlled endocrine problems. The restoration of small diameter implants with angled abutements, in the molar areas, is not recommended. Incorrect manipulation of small components inside of the oral cavity implies a breathing and/or ingestion risk. Forcing the implant into the surgical site, other than into the one decided upon, with the instrument, might cause stripping of the screwdriver's hexagon, stripping of the implant hexagon, cold soldering of the interface, between the insertion instrument and the implant, or stripping of the implant site's walls, a situation that could compromise the effective initial fixation of the implant.

Fig. 9

TEST REPORT- - GAMMA RADIATION VALIDATION

TESTING SERVICES COMPANY

Report Date: 18/1/09

To – CUSTOMER

From – SERVICE PROVIDER m

Microbiology Devision

Starting Date – 19/11/08

Laboratory Completion Date – 15/12/08

SAMPLE – Dental Implants

Test Report

Gamma Radiation Validation of 22.5 kGy according to AAMI Tir 33:2005

Milouda Report Number – 49259, 49261, 49262, 50850
Order # 1012/08

Authorization of Report

	Name	Title	Signature
Prepared by	Dr. Ronit Ben Avraham	Head of Biology Lab	
Lab technician			
Approved by	Dr. Ronit Ben Avraham	Head of Biology Lab	

Page 1 of 9

Remarks:

1. The laboratory operates in accordance with recognized standards of the International ISO/IEC 17025 in all tests where recognition has been granted.
2. The microbiological tests are recognized and published by the Israel Board of Health.
3. The results relate to the sample tested only.
4. Laboratory results are to be used in their entirety and no part may be quoted or copied to other documents.
5. Sampling was provided by and is the sole responsibility of the customer.
6. The Israel Laboratory Accreditation Authority is not responsible for the test results.

ISRAEL Health Plants Sample Reports IS 0116 Gafta Grain And Feed Trade Association

milouda@milouat.co.il
www.milouda.co.il

Fig. 10

We, **COMPANY X** located in **LOCATION**, manufacturers of Dental Implants and accessories, have classified our:

- **Dental Implants & healing Cups & Abutments as a Class IIb**, in accordance with Rule 8, of Annex II of the Medical Device Directive 93/42EEC "All implantable devices and long term surgically invasive devices are in class IIb".
- **Dental Implants accessories & surgical kits are Class I** in accordance to rule 5 "All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device: — are in Class I if they are intended for transient use".
- **Accessories / ball attachments as Class IIa** - For those products that are being sale separately to support the patient and are being remain in the patient mouth for several weeks Can be more than 30 days), such as the healing cup are classified as Class IIa according to rule 5: All invasive devices with respect to body orifices are in Class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa."

Full Name: _____ Position: _____

Date: _____ Signature: _____

Fig. 11

Application Number: APP-00212	
Client: Global Devices	
Country: Canada	Device: Heart Monitor
Risk Class: A	Application Date: 4/12/2011
Documents:	
1-Executive Summary	Download
2-Company Profile	Download
3-Device EMC	Download
4-Insurance papers	Download
5-Insurance papers-FR	File not found
6-Financial info	Download

Fig. 12

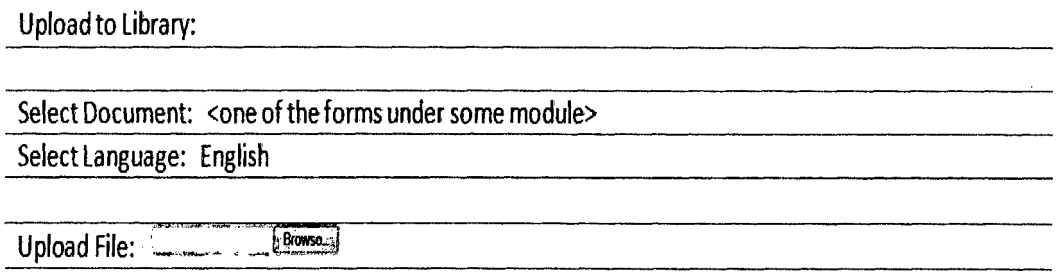
Upload to Library:
Select Document: <one of the forms under some module>
Select Language: English
Upload File:
Browse...

Fig. 13

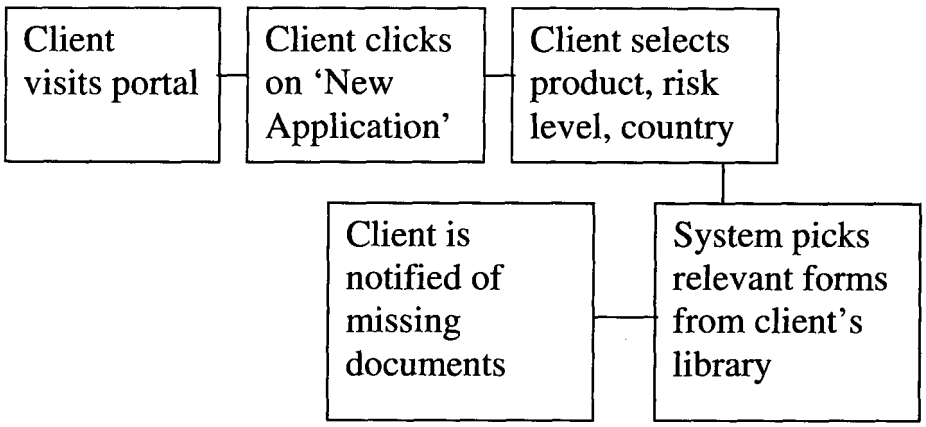
Client visits portal
Client clicks on 'New Application'
Client selects product, risk level, country
System picks relevant forms from client's library
Client is notified of missing documents

Fig. 14

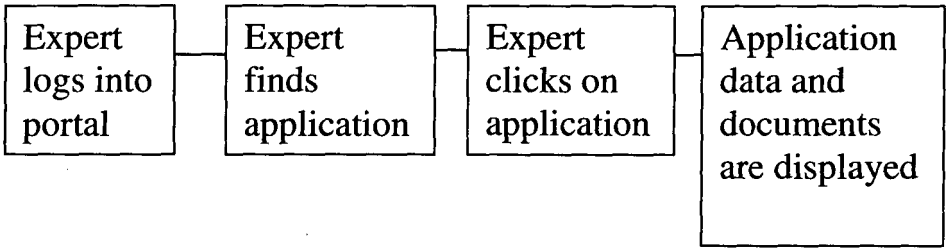
Expert logs into portal
Expert finds application
Expert clicks on application
Application data and documents are displayed

Fig. 15

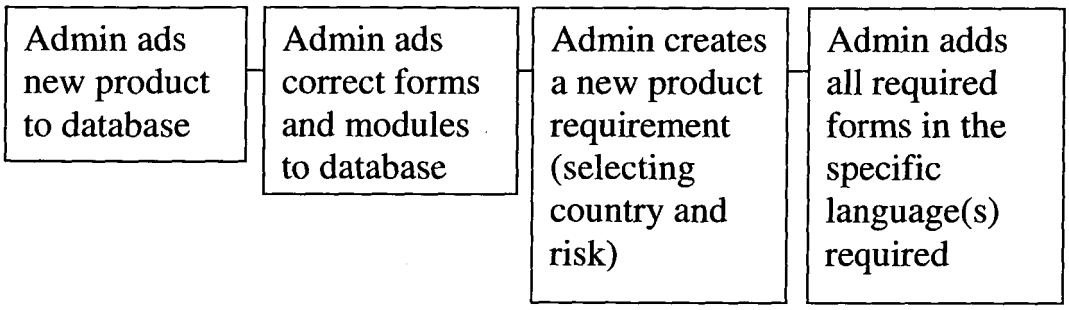
Admin ads new product to database
Admin ads correct forms and modules to database
Admin creates a new product requirement (selecting country and risk)
Admin adds all required forms in the specific language(s) required

Fig. 16