

FUJI CORPORATION

ロボット介護機器開発等推進事業 (海外展開) 令和6年度成果報告

RYU TAKAHASHI

2025 March 11

- Agenda -

①  株式会社FUJIのテーマ

②  米国上市に必要な要素

③  活動と成果 

④  今後の活動

株式会社FUJIIのテーマ



移乗サポートロボットHugの 海外展開を目的とする研究



対象国 : アメリカ合衆国

対象製品 : Hug T1-02

目標 : アメリカ市場での上市

米国上市へ必要な要素



米国上市へ必要な要素

規格認証
販売登録



設計・仕様



販路形成



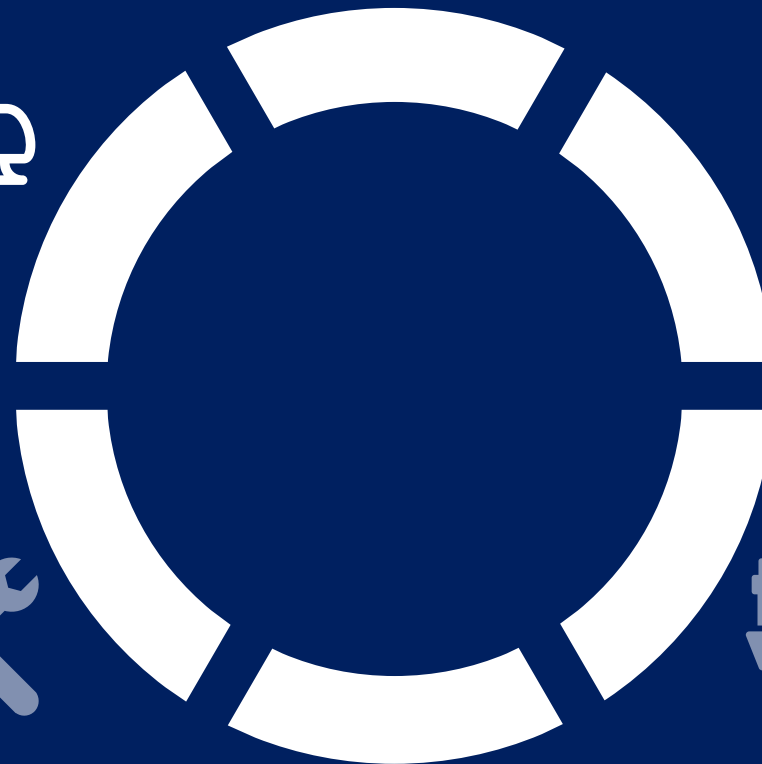
マーケティング



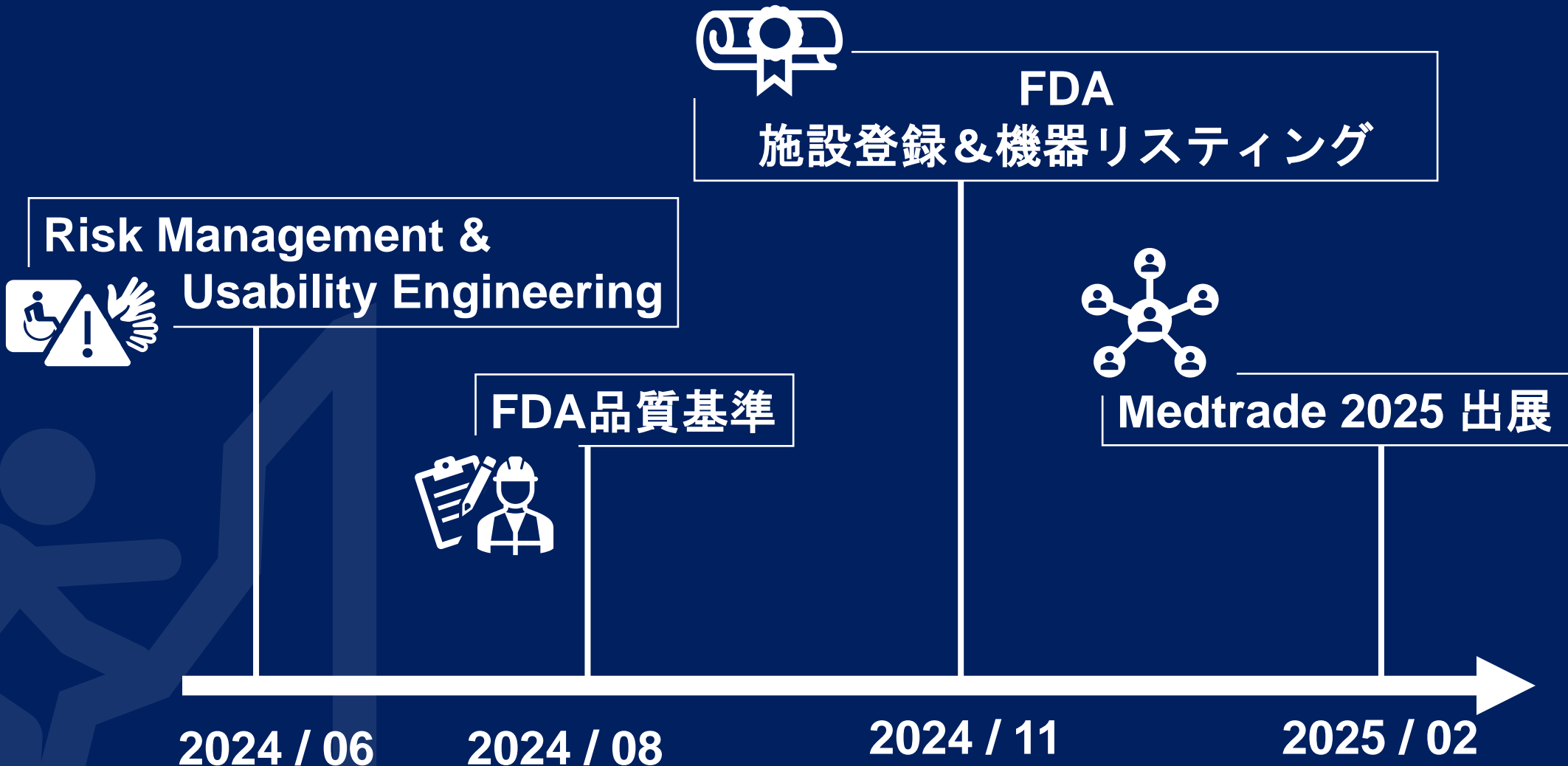
輸出・生産体制



CS体制構築



🕒 令和6年度の活動

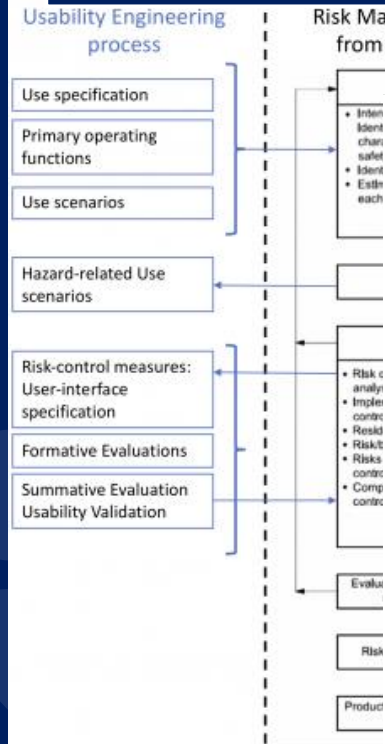




Risk Management & Usability Engineering



IEC 62366-1



ISO 14971

8
T 14971 : 2020 (ISO 14971 : 2019)

である。特に複雑な医療機器において、早い段階でのハザード及び危険状態の特定を可能にする。

注記3 リスクマネジメントプロセスの概略図を図1に示す。特定のライフサイクル段階によってリスクマネジメントの各要素は、様々な重点をもつことがある。リスクマネジメント活動は、医療機器によって必要な場合、繰り返し又は分割した複数段階で実施することも可能である。附属書Bに、リスクマネジメントプロセスの各段階の更に詳細な概要を示す。

適合性は、適切な文書の設置によって確認する。

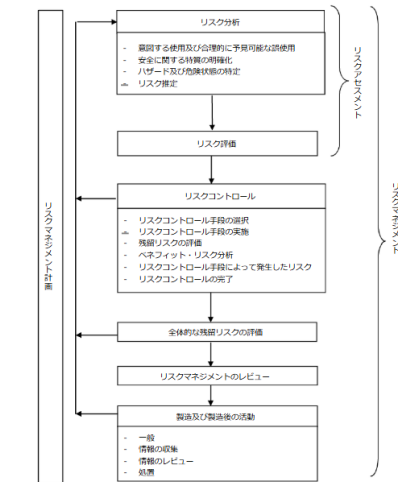


図1-リスクマネジメントプロセスの概略図

設計成果 報告書作成

Risk management report

Product: Mobility support robot
Type/Model: T1-02
Effective date: 2019-04-12
Version: V1.0

T1-02
Electric Transfer Assist Robot

Usability Engineering Report

Prepared by	Checked by	Approved by
Hideaki Nomura	Ryu Takahashi	Nobuyuki Nakane
2019-04-10	2019-04-11	2019-04-12

Company Name: FUJII Corporation/ADTEK FUJII

危害の重大さ: S	危害の発生確率: F + Ps + A										
	3	4	5	6	7	8	9	10	11		
死亡につながる	5	15	20	25	30	35	40	45	50	55	
回復に長期治療(1月以上)を要す	4	12	16	20	24	28	32	36	40	44	
回復に治療措置を要す	3	9	12	15	18	21	24	27	30	33	
応急手当てで回復可能	2	6	8	10	12	14	16	18	20	22	
対処不要(一時的な痛み等)	1	3	4	5	6	7	8	9	10	11	

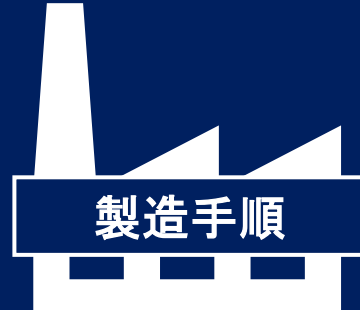


FDA品質基準 対応

Quality Management System High Level Documents and Procedures (includes associated Forms and Logs)	Relevant Regulatory Requirement (21 CFR Part 820)	Description	Do you have a procedure meeting (or right already)?	Comments
Quality Manual	820.14, 820.5	Overarching document that outlines the QMS	yes	Being reviewed by Asuka
Quality Policy and Objectives	820.20 (a)	Describes the company's quality policies and their objectives	yes	QIM being reviewed by Asuka
Control of Documents and Records	820.40, 820.181, 820.184, 820.186	Defines the controls needed to create, review, release, revise, and approve documents and records and to establish the minimum requirements for the identification, storage, protection, retrieval, retention time and disposition of documents and records	yes	Undergoing machine translation
Management Responsibility and Review	820.20 (c)	Describes the responsibilities of Management during Management Review, Quality Planning, and the implementation and improvement of the QMS	yes	QIM being reviewed by Asuka
Measuring and Monitoring of Product and Processes	820.22 (c)	Establishes a process for monitoring, measuring and analyzing QMS-related	yes	QIM being reviewed by Asuka
Competency, Awareness, and Training	820.20 (b)	Describes the process for assessing competence, awareness and training requirements for all personnel operating under the QMS to ensure that all operators are trained to adequately perform their assigned responsibilities	yes	No to answer questions from Asuka

CFR/QSR 及び コンサルティング

ISO9001 及び 社内・製造手順



製造手順

内部監査 ファクトリーツアー



CFR/QSR準拠 社内・製造手順 + 設計資料

P-010726-SP-H-Procedure, Medical Device Registration, Reporting and Recalls for USA, Fuji.docx	2024/05/09/9:59	Microsoft Word ...	277 KB
P-010729-FM-D-Health Hazard Evaluation Forms, Fuji.docx	2024/05/09/9:59	Microsoft Word ...	51 KB
P-010730-FM-D-Advisory Notice Form, Fuji.docx	2024/05/09/9:59	Microsoft Word ...	12 KB
P-010731-MO-D-UD Generation and Management, Fuji.docx	2024/05/09/9:59	Microsoft Word ...	272 KB
P-010733-SP-D-Feedback and Complaint Handling, Fuji.docx	2024/05/09/9:59	Microsoft Word ...	58 KB
P-010734-FM-D-Feedback and Complaint Report, Fuji.docx	2024/05/09/9:59	Microsoft Word ...	44 KB
P-010735-LG-B-Feedback and Complaint Log, Fuji.xlsx	2024/05/09/9:59	Microsoft Excel 7...	37 KB
P-010736-FM-D-Medical Device Reporting (MDR) Decision Tree.docx	2024/05/09/9:59	Microsoft Word ...	141 KB
P-011036-SP-B-QMS-SQP-424 Control of Documents and Records (Fuji Corporation).docx	2024/05/09/9:59	Microsoft Word ...	66 KB
P-011207-SP-C-QMS-SQP-438 Infrastructure, Workpace, Contamination Control (Fuji Corporation).docx	2024/05/09/9:59	Microsoft Word ...	64 KB
P-011208-SP-C-QMS-SQP-731 Design and Development (Fuji Corporation).docx	2024/05/09/9:59	Microsoft Word ...	145 KB
P-011209-SP-D-QMS-SQP-731 Risk Management (Fuji Corporation).docx	2024/05/09/9:59	Microsoft Word ...	146 KB
P-011210-SP-D-QMS-SQP-738 Servicing, Repair, and Modifications (Fuji Corporation).docx	2024/05/09/9:59	Microsoft Word ...	40 KB
P-011311-SP-C-QMS-SQP-738 Engineering Change Control (Fuji Corporation).docx	2024/05/09/9:59	Microsoft Word ...	71 KB

P-011223-FM-B-QMS-FRM-755 Work Order Form (Fuji Corporation).docx	2024/05/09/9:59	Microsoft Word ...	42 KB
P-011224-FM-A-QMS-FRM-750 Deviation Acceptance Form (Fuji Corporation).docx	2024/05/09/9:59	Microsoft Word ...	46 KB
P-011225-LG-A-QMS-LST-750 Deviation Acceptance Log (Fuji Corporation).xlsx	2024/05/09/9:59	Microsoft Excel 7...	29 KB
P-011226-FM-A-QMS-FRM-751 Product Release Authorization Form (Fuji Corporation).docx	2024/05/09/9:59	Microsoft Word ...	45 KB
P-011227-FM-B-QMS-FRM-752 Certificate of Conformance (Fuji Corporation).docx	2024/05/09/9:59	Microsoft Word ...	41 KB
P-011228-FM-A-QMS-FRM-001 QMS Software and Hardware Validation Form (Fuji Corporation).docx	2024/05/09/9:59	Microsoft Word ...	54 KB
P-011275-SP-C-QMS-SQP-732 Design Transfer to Production (Fuji Corporation).docx	2024/05/09/9:59	Microsoft Word ...	61 KB
P-011276-SP-B-Corrective and Preventive Action Document.zip	2024/05/09/9:59	圧縮 (zip 形式) 7...	185 KB
P-011283-FM-A-QMS-FRM-502 Memo Template (Fuji Corporation).docx	2024/05/09/9:59	Microsoft Word ...	46 KB
P-011284-LG-A-QMS-LST-760 Calibration Log (Fuji Corporation).xlsx	2024/05/09/9:59	Microsoft Excel 7...	37 KB
P-011291-FM-A-QMS-FRM-756 ECR Form (Fuji Corporation).docx	2024/05/09/9:59	Microsoft Word ...	56 KB
P-011294-QM-C-Quality Manual, (Fuji Corporation).docx	2024/05/09/9:59	Microsoft Word ...	343 KB



FDA 施設登録 & 機器リスティング



U.S. FOOD & DRUG ADMINISTRATION
(米国食品医薬局) に、医療機器として
登録を行わなければならない

登録に必要な情報が多く存在

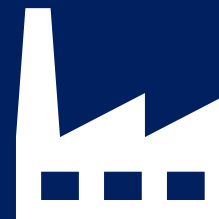
- ・ 機器分類
- ex : Non-AC-powered patient lift (Hug)
- : Portable air compressor
 (携帯エアコンプレッサー)
- : Aortic Stent (大動脈ステント)

- ・ GS1 GTIN
- ・ DUNS Number
- ・ U.S Agent
- ・ Initial Importer

etc...



設計・開発施設である
株式会社 FUJI 本社



製造・梱包施設である
ADTEK FUJI 本社



登録



Medtrade 2025 出展

MEDTRADE EXPO + CONFERENCE



2025 / 02 / 19 - 20
in Kay Bailey Hutchison
Convention Center
Dallas, TEXAS



S	E	F	H	J	K	L	O	
2	SEITZ FELDMAN	Member	DEERFIELD BEACH, FL	#1 MEDICAL EQUIPMENT & SUPPLY	OWNER	breit@medsupply.com	954987526	Florida DMEC supplier Interested in better to show to care facilities Consider DMEC, set up business with our medical aging care Likes design, \$7,000 is more expensive than Hoyer, but design is interesting Has lots of worldwide specs in Canada Very interested in becoming distributor, especially in Europe (Germany) and western US Could assist with registration in Europe Really likes the design Would like to have 2 or 3 shelves (on cart) for own warehouse Would like req. review, logo and demo and sell Does free articles for new product releases, just email some pictures and text Answer business Has contract to supply to US government, VA Needs special pricing for government contracts (can keep secret from competitors) Really likes Huq due to unique design Sells millions of lbs on their website Can market and sell online SDB and SDB Work with manufacturer to create educational and training materials
3	SIYAN HUGHES	Attendee	MIDHURST, ON Canada	HUGHES HOME HEALTH	OWNER/OPER	forhuq@hugheshomehealth.ca	783303594	
4	DENNIS LEE	Exhibitor	BRIDGE, CA	WILLETTE AMERICA CORP		dennis.lee@willette.com		
6	GLENN KNOWLES MEG HENDON	Attendee Exhibitor	CUMMING, GA BIRMINGHAM, AL	COMPRESSION THERAPY SYSTEMS LLC HOMECARE MEDIA		dglenn@compressiontherapysystems.com meg.hendon@homedcaremedia.com	770628083	高級、在宅ケアを強化してオンライン
7	MYO TUN	Attendee	VISTA, CA	AVENUE MEDICAL EQUIPMENT, INC.	PRESIDENT	Mun@avenue.com	949887444	
9	PAULINE FEDDO	Attendee	WATKINSVILLE, GA	RDHABART	CEO/FOUNDER	pauline.feddof@rdhabart.com	786231144	リハビリの腕、人材確保、オンラインストア Has a particular patient who Huq would probably suit Would like to see the health Also wants to put in touch with HMR healthcare, a DMEC in NY NJ Has a lot of health care cases HMR wants unique products that can help them stand out \$6,7000 per equipment for home care self pay Might work on trial Sell to hospitals across US Might be interested in a demo DMEC Texas Very interested, please let them know after FDA approval
9	PINNY MOST	Attendee	LAKEWOOD, NJ	MOST CARE OPTIONS	OWNER	Penny@mostcareoptions.com	732608992	
9	TANGISHA CARTER	Attendee	HOUSTON, TX	CJ MEDICAL ENTERPRISES	CEO/FOUNDER	Carter@cjmed.com	832428334	

多くのディストリビュータや
ステークホルダと情報交換
北米の介護機器商流についても確認

23	BONNY KO WING T	Attendee	KWAI CHUNG, Hong Kong	MEDMART		bonny@medmart.com.hk	85296830780	特別申し込み Created by: RYU TAKAHASHI Date Created: 02/19/2025 1:46pm
24	BRITANY SMITH	Attendee	KNOXVILLE, TN	ABCO MEDICAL SUPPLY		brifany01@abco.com	865278631	特別申し込み Created by: RYU TAKAHASHI Date Created: 02/19/2025 2:41pm
25	BRYAN SOLOMAN	Exhibitor	LEAFYETTE, GA	FLEX-A-MED, INC.		brman@flexamed.com		Checking Medtrade for own therapy product that they distribute (from Europe) Knows care home provider who might be interested in Huq Created by: David Brown Date Created: 02/19/2025 12:53pm



今後の活動

北米での販売活動の拡大



日本を超えるポテンシャルを持つ地域として



- 展示会出展の継続
- ディストリビュータへのさらなる接触
- 商流の構築、および多角化



などによりマーケット拡大を目指す

大型Hugの検討



日本と比較し、
困りごとの大きさを実感

欧州やその他地域への展開



アメリカ市場で得たノウハウを活かし、
ヨーロッパ市場への展開方法を検討

