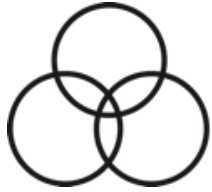




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Temmuz 2016

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TÜRKİYE



GÜNDEM

Bölüm I: Yeni iş yapış şekli !

Zamandan ve paradan tasarruf yaparak çok sayıda pazara nasıl girilir:

- LICENSALe.COM® vasıtasıyla basitleştirilen küresel MedTech kayıtları
- Soru & Cevap

Bölüm II: ABD – FDA; Mevcut uygulamalar;
UDI etiketleme gereklilikleri nasıl karşılanır.

Bölüm III: Açık toplantı

Türk MedTech endüstrisinin pazara erişim zorlukları.

T

SAĞ EL, SOL ELİN NE BİLİYOR MU?



MEVZUAT ONAYINA YÖNELİK ENTEGRE STRATEJİ



ONAY



DEĞER

KARMAŞIKLAŞAN MEVZUAT ÇERÇEVESİ



YENİ MEVZUATIN ZORLUKLAR

Ruhsatlandırma ve Piyasa ile ilgili istihbarat eksikliği

Yerel iş ortakları ve tedarikçilerin eksikliği

Yüksek ve Değişken maliyetler

Uzun süren pazara çıkış süresi

Lisans mülkiyeti

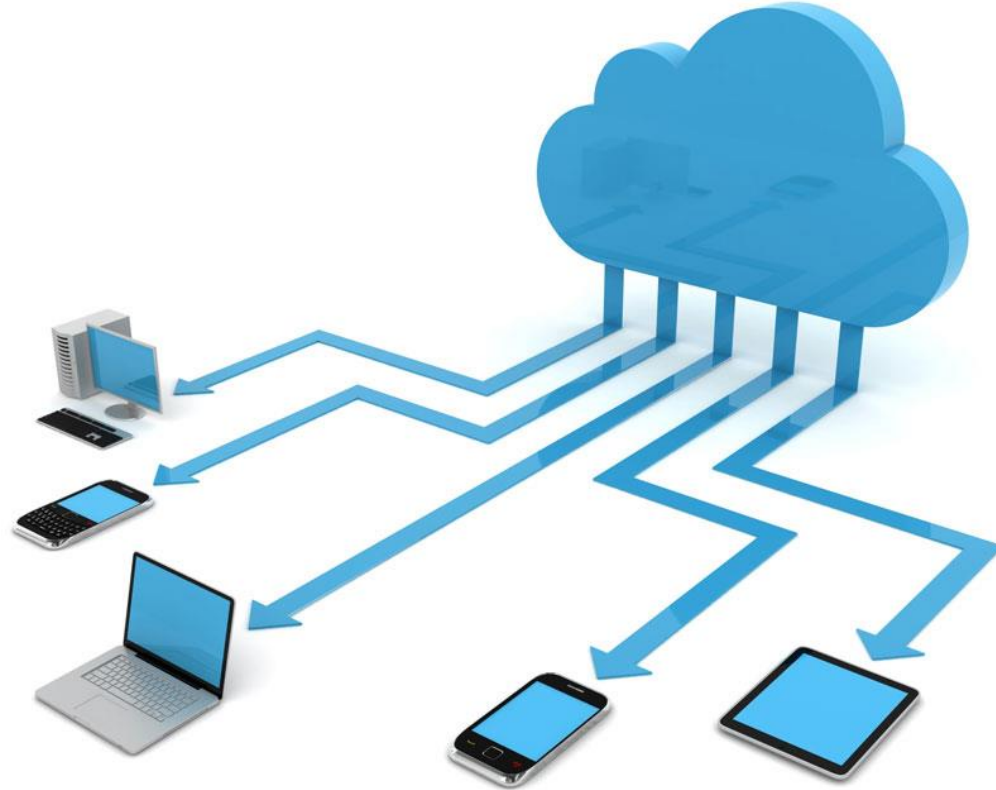
Sınai Mülkiyetin Kontrolü

İletişim

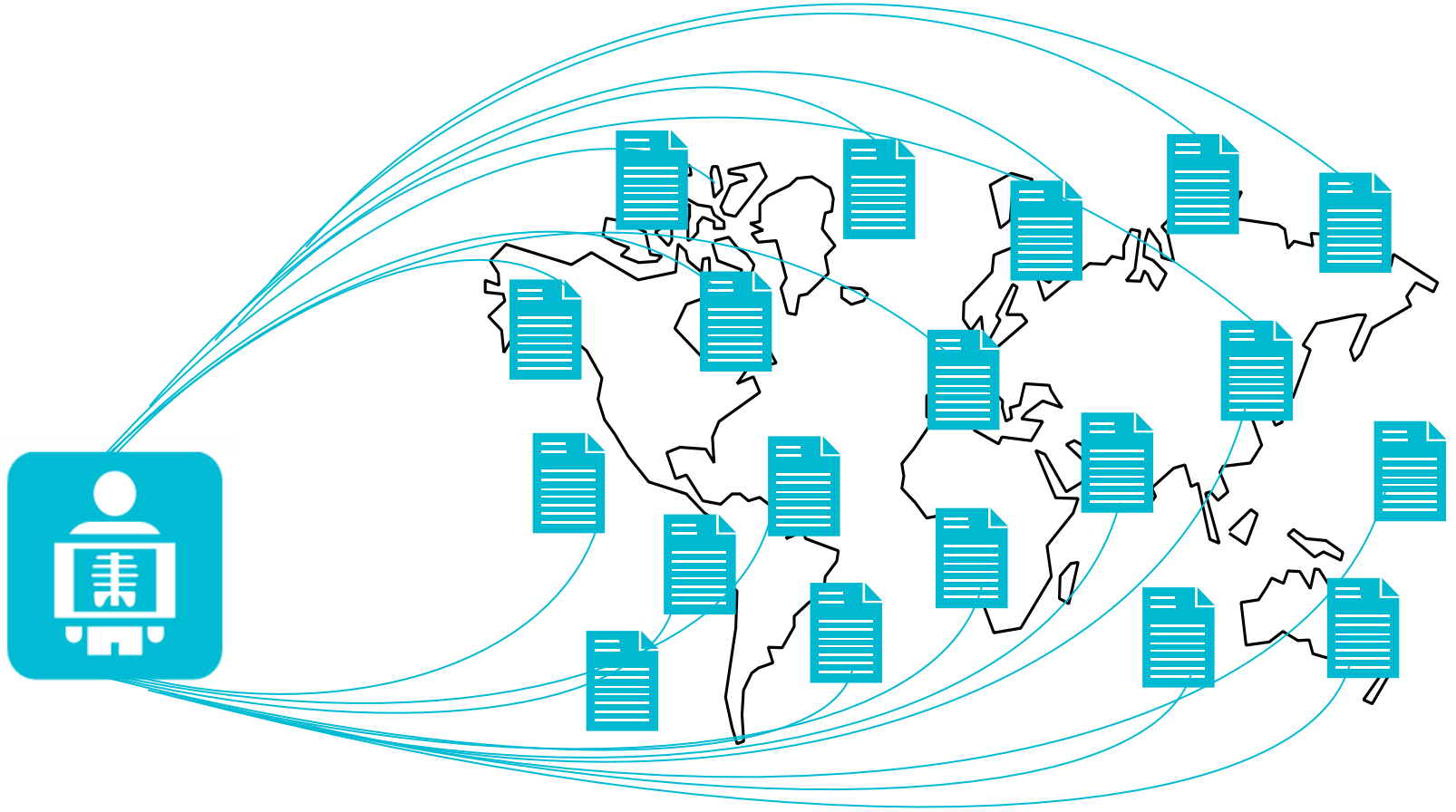
Satış sonrası faaliyetler



YENİ SORUNLAR YENİ ÇÖZÜMLERLE ÇÖZÜLÜR



BULUT Teknolojisi – KÜRESEL PAZARA AÇILMA STRATEJİNİZDE YENİ BİR OYUNCU



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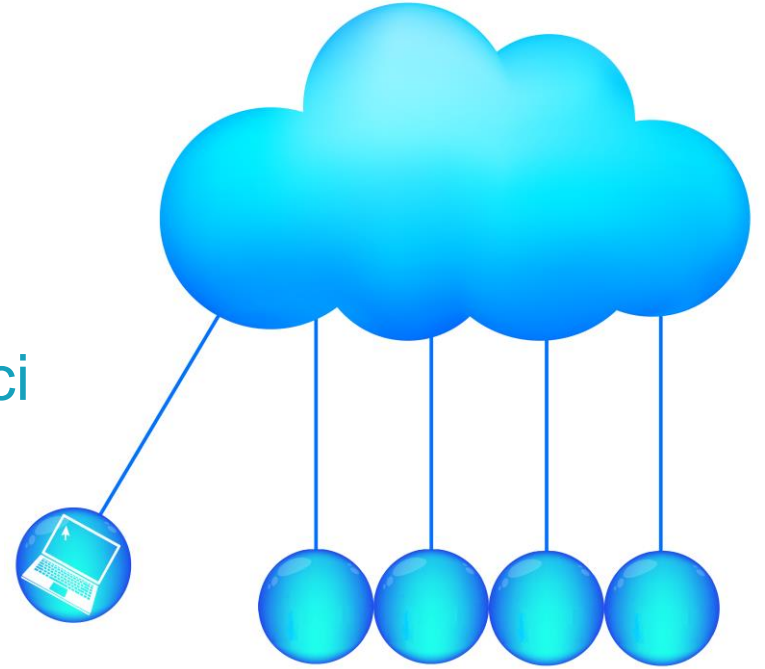
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LICENSALE.COM® PAZARA AÇILMA ve RUHSATLANDIRMA STRATEJİNİZİ NASIL BİRLEŞTİRİR?

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AS TEST - Device Label.docx	Labeling - Device
AS TEST - ISO certificate.docx	Manufacturer's QMS Certificates
Accessories.docx	Product accessories
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IFU-User Manual-DEMO.docx	Labeling - IFU or User Manual
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SPANISH-Device Label-DEMO.docx	Labeling - Device
SPANISH-Package Label-DEMO.docx	Labeling - Package
SPANISH-QMS Legal-DEMO.docx	Manufacturer's QMS Certificates
SPANISH-Product Description-DEMO.docx	Product description and intended use
TAG-LEGAL-Device Label-DEMO.docx	Labeling - Device
TAG-IFU-User Manual-DEMO.docx	Labeling - IFU or User Manual
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APPDOC-0027458	Authorized Representative appointment letter	English	Apostille & Embassy	AR Agreement2.docx (v0 @ 4/15/2013 2:46 PM)	Approved	@ 8/26/2014 5:52 PM
APPDOC-0027459	Certificate of Free Sale	French	Notarized	Certificate of Free Sale.docx (v0 @ 5/7/2015 11:59 AM)	Awaiting Release	@ 6/21/2015 12:18 PM
APPDOC-0027461	US - FDA Approval/Clearance	English	Notarized	- Please Choose -	Document Missing	No Notes
APPDOC-0027463	Product description and intended use	English		Description.docx (v0 @ 7/26/2012 11:46 AM)	Approved	No Notes
APPDOC-0027464	Labeling - IFU or User Manual	English		IFU (v0 @ 8/12/2013 12:45 PM) (Replace)	Awaiting Release	@ 4/14/2015 1:50 PM
APPDOC-0027465	Labeling - Device	English		AS TEST - Device Label.docx (v0 @ 5/26/2015 12:58 PM)	Approved	No Notes
APPDOC-0027466	Summary of clinical study results	English		- Please Choose -	Awaiting Release	No Notes
APPDOC-0027467	Evidence of release through QA	English		- Please Choose -		No Notes
APPDOC-0027468	Description of the manufacturing process	English		Manufacturing Process - DEMO.docx (v0 @ 9/2/2015 12:57 PM) (Replace)		No Notes
APPDOC-0027469	Risk analysis	English		Risk Analysis - DEMO.docx (v0 @ 9/2/2015 12:57 PM) (Replace)		No Notes
APPDOC-0027470	Evidence of established procedures and systems for post-marketing surveillance	English		- Please Choose -		No Notes
APPDOC-0030877	EC Certificate (CE Mark)	English	Notarized	EC Certificate.docx (v0 @ 7/13/2012 3:54 PM)	Approved	No Notes

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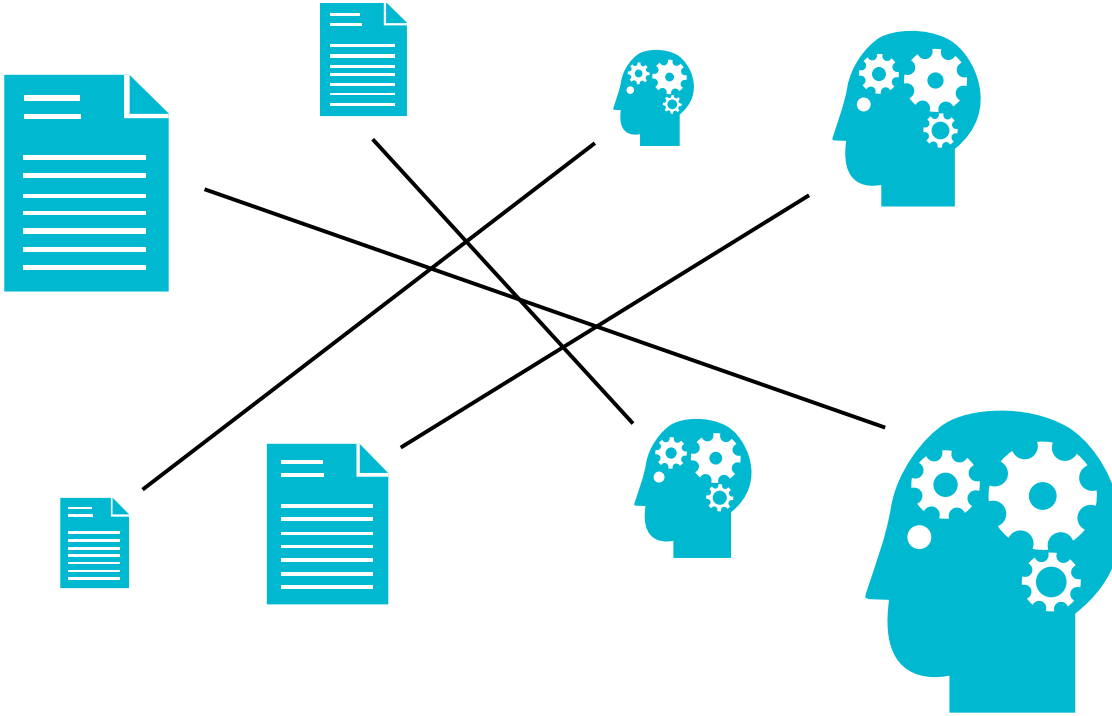
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APPDOC-0062658	Certificate of Free Sale	Spanish (Castilian)	Apostille	SPANISH-CFS-DEMO.docx (v0 @ 8/13/2015 6:09 PM)	Approved   	No Notes
APPDOC-0062659	Manufacturer's QMS Certificates	Spanish (Castilian)	Apostille	SPANISH-QMS-Demo.docx (v0 @ 8/13/2015 6:14 PM)	Approved   	No Notes
APPDOC-0062660	ISO 13485 Certification	Spanish (Castilian)	Apostille	ISO 13485 - DEMO.docx (v0 @ 8/13/2015 6:15 PM)	Approved   	No Notes
APPDOC-0062661	Description of the manufacturing process	Spanish (Castilian)		SPANISH - Manufacturing Process - DEMO.docx (v0 @ 8/13/2015 6:17 PM)	Approved   	No Notes
APPDOC-0062662	Product description and intended use	Spanish (Castilian)		SPANISH-Product Description- DEMO.docx (v0 @ 8/13/2015 6:17 PM)	Approved   	No Notes
APPDOC-0062663	Product Specifications / Drawings	Spanish (Castilian)		SPANISH - Specs and Drawings - (v0 @ 8/13/2015 6:18 PM)	Approved   	No Notes

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