WEBINAR
Content Requirements Under MDR...and What You Can Do About It!
$705 Million and Growing

1992 Year Founded

26 Years of Growth

90% of Fortune 500 Companies

ISO 9001, ISO 13485, ISO 14971, U.S. Pat. No. 8,140,322

80% of Top-20 Device Makers

170+ Languages Supported

5000+ Global Employees

90 Cities Worldwide

34 Countries

6 Continents
MDR/IVDR: “A CONTENT TSUNAMI”

“...the MDR/IVDR are expected to increase both the volume and velocity of device-related content, while also increasing the amount of regulatory scrutiny applied.” – Content Under MDR_Initial Findings (TransPerfect & Qserve)

• **PMS Activity**
  – New Reporting
  – Volume/Velocity
• **Labeling**
  – Volume/Velocity
  – New Types
• **Clinical Data**
  – Volume/Velocity
• **Translation**
  – “Clearly comprehensible”
• **Marketing**
  – Controlled
  – Consistent
• **Training**
  – Volume/Velocity
  – eLearning
A ONCE & FUTURE INCREASE

Back of the envelope estimates JUST FOR THESE PLANS/REPORTS (MDR ONLY)
(not including Supply Chain, IT, Vigilance, UDI, Legal, 13485:2016, MDSAP ...)

N = # of TF/CER

**Remediation**
- CER updates = 30 x N = 30N days
- PSUR creation = 20 x N = 20N days
- PMCF report = 10 x N = 10N days
- SS&CP creation = 15 x N = 15N days
- TF remediation = 7 x N = 7N days

**TOTAL = 82N days**
- N=1, 82 days (= 0.4 FTE)
- N=10, 820 days (= 4 FTE)
- N=100, 8200 days (= 40 FTE)

**Maintenance**
- CER updates = 10 x N = 10N days
- PSUR revisions = 10 x N = 10N days
- PMCF revisions = 5 x N = 5N days
- SS&CP revisions = 3 x N = 3N days
- RMR revisions = 1-5 x N = 1N-5N days
- TF maintenance = 1-3 x N = 1N-3N days

**TOTAL = 30N – 36N days**
- N=1, 30-36 days (= 0.15 to 0.18 FTE)
- N=10, 300-360 days (= 1.5 to 1.8 FTE)
- N=100, 3000-3600 days (= 15 to 18 FTE)

*Assume 1 FTE = 200 days*

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320% increase in number of annual updates for Technical Files and related documents (including labeling)

$150,000 per product language remediation cost for Class II implantable (22 languages, Labeling, PMS Reporting, Training, Marketing)
A CURE FOR THE MDR/IVDR HEADACHE

“Take two and call me in the morning...”
ENCOMPASS SOLUTION FOR MDR/IVDR CONTENT

Structured Content

XML CCMS
Single Source

</XML>
(10-100x)

Process Automation

TERM MANAGER
PROCESS AUTOMATION
TM SERVER
REVIEW PORTAL

AI ENGINE

• Supplier agnostic
• Modular
• Interoperable (API)

REVIEWERS

BUSINESS USERS

Production Support
Reviewer Training
“IMPOSSIBLE WITHOUT XML”

- **Stryker:**
  25% overall cost savings; 35% TAT improvement versus document-based

- **Medtronic:**
  “10x the work with the same headcount”

- **Tyco > Covidien Rebranding:**
  30+ DTP operators, 18 months (XML = 6 weeks, no increase in headcount)
ROBOTS TO THE RESCUE: TRANSLATION PROCESS AUTOMATION

Benefits

• Asset Leverage
• Resource Coordination
• Cost, Time Reduction
• Improved Quality
TRANSLATION MANAGEMENT: MULTIPLE RESOURCES, ONE SYSTEM

Process Automation

BUSINESS USERS

GLOBALink PROJECT PORTAL

TERM MANAGER

PROJECT DIRECTOR

TM SERVER

REVIEW PORTAL

TRANSFollowers

REVIEWSERS
**TRANSLATION MEMORY ASSETS**

<table>
<thead>
<tr>
<th>MATCH TYPE</th>
<th>TEXT</th>
<th>TM MATCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>FUZZY MATCH!</td>
<td>Postoperative care is the responsibility of the healthcare professional.</td>
<td>Postoperative care is the responsibility of the medical professional.</td>
</tr>
<tr>
<td>EXACT MATCH!</td>
<td>Widest Range of Sizes, All In One System</td>
<td>Widest Range of Sizes, All In One System</td>
</tr>
</tbody>
</table>

- Your Intellectual Property
- Never Pay to Translate the Same Phrase Twice
- Improved Quality and Consistency
- Faster Time-to-Market
### SPEND STATS

#### Spend & Volume by LP (Without Locale)

<table>
<thead>
<tr>
<th>Total Revenue</th>
<th>Jobs</th>
</tr>
</thead>
<tbody>
<tr>
<td>$116,493.90</td>
<td>45</td>
</tr>
<tr>
<td>$114,600.79</td>
<td>44</td>
</tr>
<tr>
<td>$97,637.83</td>
<td>38</td>
</tr>
<tr>
<td>$72,219.65</td>
<td>36</td>
</tr>
<tr>
<td>$70,292.75</td>
<td>32</td>
</tr>
<tr>
<td>$69,407.66</td>
<td>32</td>
</tr>
<tr>
<td>$92,451.03</td>
<td>30</td>
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<tr>
<td>$61,412.96</td>
<td>30</td>
</tr>
<tr>
<td>$51,186.96</td>
<td>28</td>
</tr>
<tr>
<td>$51,396.02</td>
<td>28</td>
</tr>
<tr>
<td>$50,187.36</td>
<td>26</td>
</tr>
<tr>
<td>$48,699.55</td>
<td>26</td>
</tr>
<tr>
<td>$48,090.96</td>
<td>24</td>
</tr>
<tr>
<td>$32,945.68</td>
<td>23</td>
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<tr>
<td>$12,366.54</td>
<td>21</td>
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<tr>
<td>$11,021.24</td>
<td>19</td>
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<tr>
<td>$8,207.90</td>
<td>18</td>
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<tr>
<td>$6,004.66</td>
<td>18</td>
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</table>

#### Unit of Measure

<table>
<thead>
<tr>
<th>Total Revenue</th>
<th>Quantity/Units</th>
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<tbody>
<tr>
<td>$706,606.85</td>
<td>1,933,002</td>
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<tr>
<td>$1,069,549.09</td>
<td>19,471</td>
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<tr>
<td>$747,860.82</td>
<td>4,831</td>
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<tr>
<td>$149,379.75</td>
<td>2,566</td>
</tr>
<tr>
<td>$2,515.00</td>
<td>27</td>
</tr>
</tbody>
</table>

#### Revenue Trend by LP (Without Locale)

#### Job Volume Trend by LP (Without Locale)
AI-ASSISTED TRANSLATION
“What first attracted me to TransPerfect’s AI solutions was the cost savings while maintaining the same level of translation quality. Now that we have successfully converted our process to AI, I’m happy to report we’ve realized 15% savings and 30% turnaround reduction with the same quality. Overall, my experience has been that the AI-supported process works even better than expected!”

- Rainer Degener, Director of EMEA Customer Service at IBA Dosimetry, GmbH

• ISO 18587 Feasibility Evaluation
  – Key considerations: Language; content type
  – Primary content types: Informational (PMS triage); labeling (IVD); Tech File; QMS
<table>
<thead>
<tr>
<th>Automation Cost/Benefit</th>
<th>Implementation Effort</th>
<th>Implementation Investment</th>
<th>Post-Implementation Return On Investment</th>
</tr>
</thead>
<tbody>
<tr>
<td>AI-Enabled Translation</td>
<td>![Gear Icon]</td>
<td>$</td>
<td>Reduce (For applicable languages):</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Project Translation Costs 15-20%</td>
</tr>
<tr>
<td></td>
<td>![GlobalLink AI Icon]</td>
<td></td>
<td>• Project Turnaround Times 25-35%</td>
</tr>
<tr>
<td>Process Automation;</td>
<td>![Gym Icon]</td>
<td>$</td>
<td>Reduce:</td>
</tr>
<tr>
<td>Consolidated Linguistic</td>
<td></td>
<td></td>
<td>• Project Translation Costs 10-15%</td>
</tr>
<tr>
<td>Assets</td>
<td></td>
<td></td>
<td>• Project Turnaround Times 5-15%</td>
</tr>
<tr>
<td>XML Single Source</td>
<td>![Hand Icon]</td>
<td>$</td>
<td>• Client Review Times 30-40%</td>
</tr>
<tr>
<td>Authoring; Automated</td>
<td></td>
<td></td>
<td>• Client Manual Effort 15-20%</td>
</tr>
<tr>
<td>Publishing</td>
<td>![Weight Icon]</td>
<td>$</td>
<td>Reduce:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Project Translation Costs 5-10%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Project Formatting Costs 50-70%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Project Turnaround Times 25-35%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Client Manual Effort 60-80%</td>
</tr>
</tbody>
</table>
TECHNOLOGY USE CASES: LABELING
DEVICE INDUSTRY’S SILENT EPIDEMIC

+27 years:
Chronic complaint

High risk:
Affects labeling and product-related content

#2 cause of recall:
Major contributor to labeling recalls.

$1.2 billion:
Annual industry cost
DOCUMENT-BASED PUBLISHING

Documentum or other Digital Asset Management (DAM) System
DOWN SIDE OF DOCUMENT-BASED

- Manual Processes: Increased risk of updates
- Silo’d: Shared content must be updated in multiple locations
- Fragmented: Repeat text with minor variations (same meaning)
UPSIDE OF AUTOMATION

• Single source, shared content
• Behavior defined with XML tags
• Separate content from format; publish automatically
MDR TRANSLATION REQUIREMENTS: YOU NEED MORE

• Linguistic Resources
• Coordination
• Automation

19 EU countries have populations similar to NY City
TECHNOLOGY USE CASES: MARKETING
STRUCTURED REVIEW

Preview pane for in-context review

Bi-lingual view ties to TM and Glossary; full audit trail for reviewer changes
REVIEW PORTAL - SEGMENT CHANGE STATS

Total no. of Segments: 180,322  Changed Segments: 16,235  Change %: 9.00%  Graded Segments: 0

Segment Change - Volume & % by Target

<table>
<thead>
<tr>
<th>Target</th>
<th>Total Segments</th>
<th>Segment %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>180,322</td>
<td>95.8%</td>
</tr>
<tr>
<td>de-DE</td>
<td>21,331</td>
<td>11.8%</td>
</tr>
<tr>
<td>fr-FR</td>
<td>12,163</td>
<td>6.8%</td>
</tr>
<tr>
<td>ru-RL</td>
<td>11,929</td>
<td>6.7%</td>
</tr>
<tr>
<td>ko-KR</td>
<td>10,662</td>
<td>5.9%</td>
</tr>
<tr>
<td>pt-PT</td>
<td>10,048</td>
<td>5.6%</td>
</tr>
<tr>
<td>sr-SE</td>
<td>9,642</td>
<td>5.4%</td>
</tr>
<tr>
<td>es-ES</td>
<td>9,471</td>
<td>5.4%</td>
</tr>
<tr>
<td>pl-PL</td>
<td>8,410</td>
<td>4.6%</td>
</tr>
<tr>
<td>de-DK</td>
<td>7,353</td>
<td>4.1%</td>
</tr>
<tr>
<td>fr-FR</td>
<td>6,924</td>
<td>3.8%</td>
</tr>
<tr>
<td>de-DK</td>
<td>5,968</td>
<td>3.3%</td>
</tr>
<tr>
<td>de-DE</td>
<td>5,947</td>
<td>3.3%</td>
</tr>
<tr>
<td>zh-CN</td>
<td>5,345</td>
<td>3.0%</td>
</tr>
<tr>
<td>de-DK</td>
<td>4,996</td>
<td>2.7%</td>
</tr>
<tr>
<td>nb-NO</td>
<td>4,996</td>
<td>2.7%</td>
</tr>
<tr>
<td>en-TW</td>
<td>3,802</td>
<td>2.1%</td>
</tr>
<tr>
<td>he-IL</td>
<td>2,896</td>
<td>1.6%</td>
</tr>
</tbody>
</table>

Change Segments by Months
TECHNOLOGY USE CASES: POST-MARKET SURVEILLANCE
GlobalLink AI Portal for MDR and IVDR Post-Market Surveillance

The GlobalLink AI Portal for automated translation provides a cost-effective document translation solution for short-turnaround projects. Compatible with 30+ different file formats, including scanned images and PDFs, the portal supports more than 40 languages. TransPerfect’s neural AI technology can be trained with glossary terms and previously translated text to customize outputs.

• Supports Increased Vigilance Requirements
INTERNATIONAL MEDIA MONITORING

CERTIFIED PROJECT MANAGERS

In addition to overseeing all of the administrative needs of the review team, TransPerfect’s project managers provide high-level consultation and oversee implementation of case specific workflows.

- Privileged reports
- Industry coverage
- Foreign language coverage
- Competitor coverage
- Search optimization

• Supports Active PMS Requirements
TECHNOLOGY USE CASES: CLINICAL DATA
**eTMF: AUTOMATION FOR CLINICAL DATA**

<table>
<thead>
<tr>
<th>Feature</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTEGRATED STUDY START-UP</td>
</tr>
<tr>
<td>ONLINE EDITING &amp; COLLABORATION</td>
</tr>
<tr>
<td>DRILL-DOWN DASHBOARDS</td>
</tr>
<tr>
<td>ADAPTIVE WORKFLOWS</td>
</tr>
<tr>
<td>SINGLE SIGN-ON TO ACTIVE DIRECTORY</td>
</tr>
<tr>
<td>REMOTE INSPECTIONS</td>
</tr>
<tr>
<td>MULTILINGUAL USER INTERFACE</td>
</tr>
<tr>
<td>ENDLESS INTEGRATION POSSIBILITIES</td>
</tr>
</tbody>
</table>

**BY THE NUMBERS**

- **24/7**  ACCESS TO YOUR TMF
- **35%**  REDUCTION IN TMF COSTS
- **>25%**  REDUCTION IN TMF PROCESS TIME
- **3/4**  REDUCTION IN TMF AUDIT TIME
MDR/IVDR CONTENT PAIN: MAKE IT STOP!

- MDR/IVDR will produce **more content volume and velocity** in key areas such as PMS, Labeling, and Clinical Data
  - Unsustainable with manual processes and document-based systems
- **Lessons from Practice:**
  - Structured automation **eliminates up to 50% of documentation cost, risk, and turnaround.**
  - AI for vigilance, informational, and other appropriate content eliminates up to **90% in translation cost** - 15-20% as part of a validated production process
  - eTMF technology cuts **35% of TMF costs.**
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