White Paper

EU Recast of the Medical Device Directives:
The Rocky Road to the new Medical Device Regulation
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1. Current EU regulatory framework for medical devices – what is it and how did we get here?

In 1985 the European Council defined the ‘New Approach’ - an innovative methodology of technical harmonization designed to remove barriers to trade and facilitate the free movement of goods with the European Union. In the spirit of this New Approach, rules governing the safety and performance requirements of medical devices were introduced in the 1990s. Subsequently, the three core Directives published by the European Council then had to be transferred into the national legislative systems of all EU member states.

The three core Directives introduced in the 1990s which form the current EU regulatory framework for medical devices (9.1) are:


Despite the requirement to transpose these Directives into law in each Member State, the binding laws, decrees and ordinances of Member States led to differences in levels of requirements and in some cases to different approaches between Member States. As a result a variety of interpretations could be observed across the European Union, with examples including the approval process of clinical investigations, safety reporting during clinical investigations and opinion on the classification of products.

Additional EU Directives (9.1) subsequently published in 2003 and 2005 supplement the regulatory framework and clarify the classification of some implantable products. These include:

- Directive 2003/12/EC on the reclassification of breast implants and the,
- Directive 2005/50/EC on of hip, knee and shoulder joint replacements,

To achieve conformity the EU publishes guidance documents including MEDDEVs and the harmonized standards such as EN ISO norms (which define methods and both product and system specific requirements). These documents undergo continuous development in order to reflect the state of the art in the quickly developing area of Medical Devices (9.2, 9.3).

One of the principles of the new approach was and is the installation of Notified Bodies. These are organizations accredited by a member state to assess whether a medical device meets relevant regulatory requirements in the EU. The Notified Bodies have the responsibility for assessing conformity of medical devices by product testing, design review, inspections, and auditing the manufacturing processes and linked QM Systems.
This approach provides a marketing decision applicable across the EU, and supports the development and life cycle management of medical devices as well as allowing appropriate timelines for supplying innovative devices to patients.

2. EU Commission initiatives to improve the application of the existing regulatory framework

The EU Commission and the appointed working groups of the EU Parliament (e.g. Environment, Public Health and Food Safety (ENVI) Committee) constantly review the regulatory framework to adapt risk-related aspects of regulation to ensure conformity of devices and predictable timelines for market access.

- One of the recent updates is the EU regulation 722/2012 defining requirements for active implantable medical devices and medical devices manufactured utilizing tissues of animal origin, which became effective on August 29, 2013 (9.1).

The Commission has agreed further immediate actions to strengthen the existing regulatory framework. For example, measures were introduced to clarify the requirements and roles of Notified Bodies, and which also relate to the requalification process of Notified Bodies that perform assessments of high risk products. Furthermore, more details have recently been announced in regard to the conditions for joint inspections performed by Notified Bodies, representatives from EU member states and the Commission. These aspects in addition to the implementation of un-announced audits are defined in the below listed European Commission Implementing Regulation and Commission Recommendation.


- Commission Recommendation on the audits and assessments performed by notified bodies in the field of medical devices 24.09.2013 (9.1).

Additionally, the Commission recommendation released in April 2013 on the unique device identification system (UDI) System should be considered:

- COMMISSION RECOMMENDATION of 5 April 2013 on a common framework for a unique device identification system of medical devices in the Union to enhance the traceability of medical devices throughout the whole supply chain contributes to patient safety by facilitating vigilance, market surveillance and transparency in this sector (9.1).

3. The recast process – why and what

The recast was initiated in 2008 with several aims including that of increasing consistency of regulation across the EU, and therefore continued to reflect the ambitions of the New Approach (9.4, 9.5). Specifically, the existing regulatory framework raised concerns for many stakeholders with respect to consistency, safety, quality, transparency, traceability and the
flow of information between manufacturers, distribution chain, member states and notified bodies.

The comparability of the quality of Notified Bodies was sometimes in doubt and the approach of their supervision was not accepted by all interested parties. There was also concern that authorities were not directly involved in the decision process for placing products on the market. Market surveillance and incidence reporting to authorities represent crucial indicators of the safety and performance of medical devices and were important factors under consideration during the recast process. Additionally, the considerable number of different device categories and types of devices required a better nomenclature to identify a device in the framework of safety reporting, field corrective actions and potential market recalls.

The Poly Implant Prostheses (PIP) breast implant scandal highlighted the consequences of extreme non-compliance. In this case the criminal approach of the manufacturer severely impacted the health and wellbeing of many women. It is therefore not surprising that stricter enforcement and additional rules for the market surveillance and the quality and power of inspections/product testing are now being discussed. Rules for an improved system to support the exchange of market surveillance information are also under review.

The call for stricter rules to ensure the validity and power of clinical data is not new. The initial intention to promote harmonization of the requirements and approvals of clinical investigations was present in the implementation of the amended EU Directives in 2007 in the laws of the EU member states with due date March 2010. Today in the EU, however, we still see considerable inconsistency in the approach and requirements of competent authorities and ethics committees in the different member states. In our view, an enhanced degree of regulatory harmonization in the EU should be considered as a necessity to remain an attractive environment for international studies. This can indirectly support prompt access to innovative devices for patients in the EU member states.

It is certain that only a continuous review of the European framework including all guidelines and technical standards is important to reflect current knowledge and experience, whilst effectively sharing this information between involved parties is an essential contribution to patient safety.

The first comprehensive picture of the result of the recast process became available on 26.09.2012 when the European Commission published the

4. **Key topics of proposed changes**

In this white paper our focus is limited to the development of the MDR. Key elements (9.6) of attention in the rework of the draft MDR were the reinforcement or introduction of

- the role of Notified Bodies,
- the role of agency and authorities,
- the implementation of expert committees such as:
  - International Medical Device Forum (IMDRF)
  - Medical Device Coordination Group (MDCG)
  - Assessment Committee for Medical Devices (ACMD)
  - Scientific Committee on Emerging and Newly Identified Health Risks
- the review of the conformity assessment procedures,
- the approaches for clinical investigation,
- the process of clinical evaluation,
- the requirements and systems for vigilance and market surveillance,
- the provisions related to marketing authorization,
- procedures to ensure transparency and traceability,
- the overall improve health and safety,
- The Implementation Acts.

These general aspects result in the following changes:

- The draft MDR merges the MD and AIMD directives,
- aspects from GHTF, MEDDEV and ISO EN 14155:2011 are partially integrated,
- announcement of 60 further implementing acts by the EU commission are defined in the draft MDR,
- the draft MDR includes 10 chapters (12 according to the proposal of the draft report from Rapporteur) with 97 articles (compared to 23 articles in the current MMD),
- the draft MDR includes 16 annexes with different numbering and titles (compared to 12 annexes in the current MMD),
- defined extended scope in the draft MDR (additional products, Annex XV),
- more definitions,
classification of products shows a general trend towards higher risk classes,

for class III product summaries or reports on safety & clinical performance need to be published in EUDAMED (European database for medical devices),

scope of use, function and content of EUDAMED is expanded,

manufactures need to appoint a qualified person,

the market approval process: for high risk products involvement of authorities and/or expert groups,

specific Annex II for the requirements on technical documentation,

EU reference laboratories shall be established,

introduction of a unique device identifier (UDI) to improve identification and traceability of devices,

centralized system for safety reporting and vigilance,

centralized approach for submission of international clinical investigations,

defined notification process for post CE studies (additional requirements),

relationship between harmonized standards and new CTS - common technical standards.

5. Timelines of the recast

After the publication of the draft MD regulation on 26.09.2012 (9.6) interested parties began their review and the European parliament appointed a rapporteur (Mrs. Dagmar Roth-Behrendt) with responsibility to collect input and proposals for any amendment to the published draft MDR. Similarly, a rapporteur for the draft IVD regulation was appointed (Mr. Peter Liese) (9.7).

This process took some time and in April and May 2013 the rapporteurs published the draft reports, and collected around 1000 amendments on the draft regulation (9.8, 9.9, 9.21 and 9.24). The draft report on the draft MDR was discussed with ENVI (Committee on the Environment, Public Health and Food Safety) on 25 September 2013 and a stricter approval system for medical devices was confirmed (9.16). An updated report was published on 09 October 2013 (9.10) in regard to the draft MDR and a day later for the IVD recast (9.11).

This report was the basis for an evaluation by the European Parliament which started on 22 October 2013. There was no final decision made during the plenary vote on the draft MDR and the report of the Rapporteur. However the centralized market approval process was opposed (9.18, 9.19, 9.25). The results of this discussion were published in the document “Amendments adopted by the European Parliament on 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on medical devices, and

This document will now undergo another intensive round of discussion in the Council of the European Union representing relevant Ministers of the EU member states. The Council is the Union's main decision-making institution (9.15), and shares the power of co-decision with the European Parliament for most of the Union's legislative acts. This is a part of the so called “Trilogy” that is performed with Council, Parliament and Commission (9.23, 9.25).

The Trilogy process has started already and the most recent meeting of the relevant Council Working Group, occurred on 6th of December 2013. Representatives of the “Bundesministerium für Gesundheit” (BMG, German Ministry for Health), for example, attended (9.20).

Due to the various points of discussion, opinions and positions the expected date for release of the final MDR is vague. The date could still be in the current legislative period of the European Parliament or could fall in the following period. In the latter case this would lead to a publication of the MDR not before April - June 2014. The transition phase for full application would be three years after coming into force (9.12, 9.23, and 9.27).

The road-map for the MDR recast from September 2012 until today is represented in Figure 1, below, which also gives a forecast of when the final MDR can be potentially expected in 2014.

Figure 1. MDR Recast – Timelines for Implementation

6. Outcome of the plenary vote of European Parliament

More details on foreseeable changes are provided below. A full picture can be found in the published document of the European Parliament, which in total proposes 347 amendments to the proposal of the Commission:


The issue has been referred back to the committee responsible. The vote has been postponed.

The main amendments adopted in plenary were as follows:

**Scope:** Parliament called for devices for **aesthetic purposes** to fall within the scope of the regulation.

Furthermore, the Regulation should not impede the continued application of measures within Directive 2002/98/EC and its five Daughter Directives setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.

**Assessment procedure for medical devices:** for high risk medical devices, such as devices in class III, implantable devices and devices incorporating medicinal products, Parliament proposes to introduce the possibility of providing an opinion on a case-by-case basis, based on the robustness of the clinical data and the evidence that the device can be safely placed on the EU market.

To this end, Members proposed the creation of an **Assessment Committee for Medical Devices (ACMD)** in order to provide the case-by-case assessment where its members deemed it necessary to ask for the review of the clinical data.

The ACMD, placed under the aegis of the Commission, should be composed of the best specialists in various medical fields, as listed in categories or subgroups, which can be subject of modifications, notably in light of technical progress. Patients’ representatives and a representative from the European Medicines Agency should also take part in the ACMD and contribute to the case-by-case assessments.

On the basis of this assessment of the clinical data, the Commission will adopt an opinion, which will be binding upon the Special notified body.

**Insurance:** to ensure that patients harmed are compensated for any damage and associated treatment as a result of a faulty medical device, that the risk of damage as well as the risk of the manufacturer’s insolvency are not shifted to patients harmed by a faulty medical device, manufacturers should be obliged to take **liability insurance with sufficient minimum coverage**.
**Notified bodies:** Members proposed to strengthen provisions relating to the personnel in the national authorities responsible for the designation and monitoring of notified bodies. Personnel must have sufficient qualifications to audit the notified bodies for which they are responsible. Moreover, it should be ensured that notified bodies have permanent "in house" competent personnel.

**Subcontracting must be the exception.** Where subcontracting takes place, notified bodies should make publicly available the names of subcontractors and the precise tasks for which they have been awarded a contract. Once a year, notified bodies should be required to send documents to the relevant national authority to enable the verification of the subcontractors' qualifications.

**Fees:** Members welcomed the Commission’s introduction of fees charged by national authorities for their activities related to the designation and monitoring of notified bodies. However, they added that those fees should be made public and comparable across Member States.

**Special notified bodies:** for high risk medical devices, such as devices in class III, implantable devices and devices incorporating medicinal products, the conformity assessment should be the responsibility of special notified bodies.

Those bodies should be designated by the European Medicines Agency (EMA) on the basis of the reinforced requirements on staff qualification and training.

The EMA shall establish, host, coordinate and manage the network of special notified bodies. The network shall contribute to the pooling of knowledge regarding medical devices.

**Labelling and disposal of single use devices:** Members considered that devices labelled as single-use should be really single-use and that there should be only two options: single-use and reusable. Furthermore, activities encompassed in the reprocessing of devices should be subject to stricter and more transparent standards.

As a result, only devices labelled as reusable should be reprocessed. To ensure the highest patient safety in the EU a list of single-use devices unsuitable for reprocessing should be set up by the Commission after consultation of the Medical Device Advisory Committee.

The reprocessing of devices encompasses various activities to ensure that a medical device can be safely reused, ranging from decontamination, sterilisation, cleaning, disassembly, repair, component replacement and packaging. These activities should be subject to comparable and transparent standards.

**Clinical investigations:** since manufacturers must collate data to prove that their devices meet performance and safety requirements, Members have introduced definitions on "performance" or "safety".

**Performance** should notably be understood broadly so as to encompass efficacy and benefit to the patient, which must be checked in cases where clinical investigations apply.

For high-risk medical devices, in the interests of increased transparency, manufacturers should draw up a report of the safety and performance aspects of the device and the outcome of the clinical evaluation.
Where clinical investigations are obligatory by virtue of the regulation, they must include \textit{randomised clinical investigations} in the appropriate target population and well-controlled investigations.

\textit{Authorisation for conducting a clinical investigation shall be granted only after examination and approval by an independent ethics committee.}

\textit{Information to patients and healthcare professionals:} Parliament called on the manufacturers of an implantable device to provide together with the device an \textit{implant card} to the patient, and to record all the information contained on the implant card in the patient’s medical records. The implant card shall also be made available by the manufacturer in an electronic format and Member States shall ensure that hospitals and clinics keep an electronic version on record.

\textit{In order to strengthen the transparency of information, Members proposed to ensure adequate levels of access for the public and healthcare professionals to those parts of Eudamed’s electronic systems which provide key information on medical devices that may pose a risk to public health and safety.}

\textit{Vigilance and market surveillance:} Parliament wanted to ensure that the \textit{reporting of incidents} and corrective measures through the electronic system includes date and place of incidents, and where available, information on the patient or user and healthcare professional, in full respect of privacy.

\textit{Coordination between Member States and Medical Device Advisory Committee (the MDCG):} the resolution proposed to set up a multidisciplinary advisory committee of experts and representatives of stakeholders and civil society organisations in order to provide scientific advice to the MDCG, and also to the Commission, and the Member States.

\textit{Penalties:} Member States are invited to set and enforce serious penalties for manufacturers that commit fraud and cheat with regard to medical devices. Those penalties should be at least as large as the revenue gains from fraud or cheating. Penalties may include imprisonment.

\textit{Delegated acts: basic aspects of this Regulation such as general safety and performance requirements, stipulations on technical documentation and the requirements for CE marking certification, as well as any amendments or additions to it, should be provided for only through the ordinary legislative procedure......... (Cite end)”

\textbf{7. Draft MDR – Feedback from Stakeholders}

Some national industry associations such as BAH (Bundesverband für Arzneimittelhersteller, the German Association for Drug Producing Industry), EUCOMED (the European Medical Technology industry association) and other interested parties provided comments (9.14, 9.16-9.27) and suggestions, examples of which are summarized below.
**Scope of the MDR**

Medical Devices containing viable biological substances will remain in the scope of the MDR, if a pharmacological, immunological or metabolic mode of action is not intended (9.20, 9.13).

Rule 21 “Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body are in class III” will be deleted. These kinds of products therefore will not fall under the stricter assessment performed by Special Notified Bodies (9.13, 9.20, 9.27). However, readers should note that the discussion on this rule is ongoing.

**Classification – Borderline Products**

In case of need for clarification or at the request of a Member State the Commission will by means of implementing acts determine whether or not a specific product, or category or group of products, including borderline products, falls within the definitions of 'medical device' or 'accessory to a medical device'. The Commission will decide on the basis of the opinions of the MDCG (Medical Device Coordination Group - representatives of authorities of the EU Member State) and the MDAC (Medical Device Advisory Committee - representatives of the industry (9.20, 9.13)).

**Rules for Single Use, Reprocessing**

In order to protect patients from cross-contamination of infectious residues from other patients, manufactures introduced single use devices to the market and these are discussed with the new MDR. Also, critical aspects of reprocessing are discussed which relate to cleaning, disinfection, sterilization and any other methods to inactivate or eliminate agents such as prions, viruses or multi-resistant bacteria. Also the design of devices is important, since some designs may not be suitable for reprocessing.

Considering these points a list of devices unsuitable for reprocessing should be set up via an implementing act (9.23).

Any reprocessing needs to fully ensure that the elimination or inactivation of infectious agents is evident. Reprocessors are not subject to any conformity assessment (9.13, 9.17, 9.18) at present. It is the opinion and recommendation of EUCOMED that the final MDR should consider a risk mitigation approach, taking into consideration all pro and cons. This should lead the definition of any new rules linked to reprocessing (9.17, 9.18). A simple transfer of liability from manufacturer/distributor/preprocessor or to user will not be sufficient.
Unannounced Inspections

The number of unannounced inspections will be defined directly in the text of the Regulation (Annex VIII). This shall ensure that across all Member States unannounced audits of manufacturers and their service providers will be performed to a comparable level and with comparable frequency. Indeed, the amendment by parliament proposes that Notified Bodies shall randomly perform unannounced inspections of each generic device group for each manufacturer at least once every five years at the relevant manufacturing sites and, if appropriate, at the manufacturer’s suppliers and/or subcontractors (Annex VIII, 9.13, 9.27).

Indeed the amendment by parliament specifies that Notified Bodies shall further ensure that unannounced inspections are conducted at least once a year of all premises at which the medical devices coming within their remit are manufactured (Annex VI, 9.13). This must be done according to a plan prepared by the Notified Body, which considers the number of generic device groups, and which is not disclosed to the manufacturer.

The Notified Bodies will pass on the additional costs of this increased inspection regime to the manufacturers, without consideration of the risk classification of the device.

With the publication of new Implementing Regulation of the European Commission on the appointment and supervision of Notified Bodies for Medical Devices together with the Commission Recommendation on audits and valuations by notified bodies for Medical Devices the announced emergency measures in this area (“Joint / Dalli Action plan”) are reflected (9.27). These current measures do correct the former weaknesses of the system already to some extent. For example, the tasks of the Notified Bodies and their evaluation are already clarified and strengthened, with further unannounced audits are foreseen. The Commission’s recommendation (24.09.2013, 9.1) states that unannounced audits should take place at least once every three years (9.13, 9.27). The final requirements and frequency for unannounced inspections will be clarified with the publication of the final MDR.

CE Marking

The future CE marking shall consist of the initials ‘CE’ accompanied by the term ‘Medical Device’ (9.13).

Rules for Market Approval

The following devices are those defined as high risk products which must undergo an assessment by a Special Notified Body (SNB) (9.27, 9.13):

- Implantable devices
- Medical devices with a drug component
- Medical devices of class IIB intended to apply and/or remove a drug (according to article 1, section 5 MDR , see rule 11)
- Medical devices that are made from non-viable or inactivated tissues or cells of human or animal origin, or their derivatives
- All other class III products

For high risk products representing in particular implantable medical devices of class III, medical devices of class IIB intended to apply and/or remove a drug and medical devices that are made from non-viable or inactivated tissues or cells of human or animal origin or their derivatives, a “case by case” conformity assessment process will be implemented. This process can be performed by the so called “Special Notified Bodies - SNB” with the participation of the so called “Assessment Committee for Medical Devices - ACMD” or the “Medical Device Coordination Group – MDCG”.

Special Notified Bodies need to apply to the EMA for authorization (see 9.13, 9.12, 9.27).

**Clinical Data and Post Market Clinical Follow Up Report**

The rules to demonstrate equivalence solely on the basis of existing clinical data will become stricter. The amended Annex XIII, Part a Point 5 notes that in the case of higher risk devices (with the exception of those used for a short term; see list in amended article 43a), clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone (9.13).

**Clinical Investigations**

In the future a centralized submission process for multi-national clinical investigations in the EU is foreseen, which will be performed via an electronic system. A member state will be selected to play the coordinating role for the approval process. Timelines for the approval process will be defined in the MDR (9.13).

The requirements for the performance of a clinical investigation are further specified, such as the patient information process for incapacitated subjects and children, and the package of documents required for the submission for authorization of clinical investigations (see amended annex XIV, part I and II, 9.13).

Furthermore the rules for post market clinical investigation with CE marked devices which impose an additional burden to patients will require a notification to Competent Authorities in the future. This is a further degree of harmonization since at the moment there are different approaches implemented in EU Member states (9.12, 9.13, 9.16 and 9.23).

The evaluation of clinical investigations by ethics committees will remain mandatory and will still fall under the responsibility of individual member states.

Post-market clinical follow-up, hereinafter PMCF, is defined as a continuous process to update the clinical evaluation. It is repeatedly stated that this shall be part of the manufacturers’ post-market surveillance plan for high risk products.
The manufacturer must analyze the findings of the PMCF and document the results in a PMCF evaluation report that will be part of the technical documentation. It has now been proposed to amend this requirement such that this report should be sent periodically to the concerned Member States. For class III devices this report shall be further reviewed by a third party or external expert under the principles of highest scientific competence and impartiality (9.13).

**Structure of MDR**

The new structure of the MDR, along with the changed numbering of articles and annexes, will inevitably represent an additional burden for all involved parties. This is because all implemented quality systems and regulatory documents will need to be reviewed, updated and will need to refer to the new applicable regulative clauses (9.13, 9.6).

**Summary**

At present nothing is cast in stone and discussions are ongoing. All stakeholders will have to wait for the final document which is expected at some time in 2014. It can be expected that even though a Regulation is immediately considered law in all member states, at the level of the EU member states several updates on country regulation will then be issued to accompany the implementation of the new MDR. These are, for example, linked to the responsibilities of ethics committees, insurance and the market surveillance/inspection process to be adopted by national authorities.

Considering the potential content of the expected final MDR the medical device industry, all interested parties will have to manage many new requirements. This will require both financial and personnel resources. Sustainable and timely provision of innovative medical devices to patients under the future regulative framework will, in the short term at least, be a challenge for the industry.

CROMSOURCE is aware of the need to prepare for the upcoming changes and is involved already with several activities to be up to date.

The CROMSOURCE Regulatory Unit, for example, provides regulatory update training for employees and via Webinars and conferences for external partners.

Furthermore, CROMSOURCE constantly reviews the progress of the regulatory framework. On a quarterly basis Regulatory Newsletters are published. If you are interested you can receive these newsletters via the CROMSOURCE website http://www.cromsource.com/latest news.
8. **About the Authors**

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After gaining her doctorate in 1990 at the Max Planck Institute for Biochemistry and Munich Technical University, Susanne started to work for TÜV SÜD in 1992 focused on quality and safety topics in life science. At TÜV SÜD, she worked as an expert in genetic engineering and biotechnology, as a QM system auditor for life science companies and as a reviewer for medical devices design dossier at a European Notified Bodies. She built a food and feed certification business and became the CEO and head of the Certification Body. Susanne joined CROMSOURCE in 2008, supporting the integration of CROMSOURCE group. She covers the role of Director of the Compliance Department and oversees Units involved in Quality Management, Regulatory Compliance, IT Compliance and Training & Qualification. Susanne applies her internationally recognized expertise to directly support clients, in particular those with challenging regulatory aspects to their projects. Susanne may be contacted at susanne.gerbl-rieger@cromsource.com.

*Kerry Dyson, Head of UK Operations, Director of Marketing and Communications*

Kerry Dyson was awarded an MSc and PhD in exercise physiology from McMaster University (Canada) and Leeds Metropolitan University (UK), respectively. After a brief academic career he joined the industry in 1999 with Innovex Ltd (part of the Quintiles group). He then worked in roles of increasing seniority within operational clinical development at Innovex and Novartis until joining Catalyst Pharma Group (CPG) in 2003, becoming Head of EU Operations in 2004. Kerry’s focus then moved from purely operational activities to include strategic and corporate developmental responsibilities. A large part of this role involved marketing and business development in across Europe and the USA. After providing significant support to the sale of the major part of CPG’s business to ICON plc, Kerry joined CROMSOURCE in 2008 with responsibility for contribution to corporate strategy, leading UK operations and business development. In 2011 Kerry became Director of Marketing and Communications whilst also retaining his role as Head of UK Operations. Kerry may be contacted at kerry.dyson@cromsource.com.
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10. About CROMSOURCE

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