OSMA BUSINESS & EDUCATION MEETING
Thursday, January 23, 2025
Renaissance Orlando at Sea World
Orlando, FL

EXECUTIVE SUMMARY
Day Two

READING OF MEETING MINUTES AND VIRTUAL HOUSEKEEPING
WELCOME AND OPENING REMARKS

Ryan Belaney, OSMA President, opened the meeting and welcomed all attendees. The meeting logistics were reviewed and the meeting guidelines read. Ryan set the stage for today's discussion and welcomed Dr. Akra to the podium to introduce the Team NB Code of Conduct session.

CODE OF CONDUCT SESSION INTRODUCTION
Bassil Akra, PhD, AKRA Team GmbH

The fragmented structure in the EU presents challenges for harmonization. The Team NB Code of Conduct was developed to help address these challenges and promote consistency and transparency. The Code of Conduct guidelines were updated in September of 2024 (Version 5.0).

TEAM NB CODE OF CONDUCT: WHAT'S NEW
Purvi Patel, PhD, Team NB

Team NB (consisting of 42 members representing 19 different countries) was founded in 2001 with the purpose to represent NBs and foster communication between industry, the EU Commission, Competent Authorities and other stakeholders as a single NB voice. Team NB participates in MDCG meetings and comments on MDCG documents. Its intent is to promote technical and ethical standards, contribute to harmonization efforts and provide training. Not all NBs are members of Team NB (39/50 NBs are Team NB members). Version 5.0 of the Code of Conduct (approved in September, 2024), removed references to the Directives, reflected compliance with MDCG guidance and Team NB papers, included an estimation of time needed for technical documentation review, clarified requirements for unannounced audits, provided a detailed explanation of re-certification requirements, included an estimation of time needed for CAPA, included examples for Structured Dialogue and changed enforcement to a complaint/ appeals process. A copy of the Code of Conduct is found on www.team-nb.org. It is mandatory for all Team members to sign the Code of Conduct and Team NB investigates if members do not follow it. Team NB established working groups in 2016 to help members be designated and allow harmonization. Task Forces are established to implement new regulations, write position papers (published on Team NB website), review MDR requirements and share NB insights with a goal toward harmonizing views and implementing best practices. Team NB also provides training to both NBs and manufacturers. Expert sessions are held to support NBs and to allow

for a harmonized approach for interpretation of requirements, for senior experts to share experience and for attendees to cascade information into their organizations to reach all reviewers.

CODE OF CONDUCT PANEL SESSION WITH NOTIFIED BODY MEMBERS
Moderator: Bassil Akra, PhD, AKRA Team GmbH
Panel Members: Marie Abdallah, GMED, Ehab Amen, GMED, Andrea Pietsch, PhD, TÜV SÜD, Ibim Tariah, PhD, SGS, Balazs Bozsik, SGS, Purvi Patel, PhD, Team NB

Are all NBs following the Code of Conduct?
A complaint/appeals process is still being developed and has just recently been implemented- time will tell.

What about appeals processes within the NBs themselves?
There is work to be done and this is the subject of a task force. It is suggested that Team NB look at best practices across all NBs. A potential opportunity for OSMA would be to look at compiling member examples/ complaints and escalate them to Team NB for input.

What is most important/ impactful in the Code of Conduct?
Harmonization and transparency are key. There is still much work to be done but we are on a good path. It is important to align (e.g., approach for interpretation of well-established technology (WET)).

How can industry provide input/feedback to the position papers? What are the communication channels?
Send a request to Francoise Schlemmer (Director of Team NB). Team NB will poll members for input and will consider addressing in the next amendment of the Code of Conduct. Consolidated industry/ association requests are encouraged, rather than individual company requests. This is more impactful.

How can Team NB ensure that knowledge is transferred to every Team NB member?
At the general deployment level, you need to have a clear deployment plan within 12 months. On the technical side, regular meetings are held to raise awareness and share learnings/positions.

Do all NBs follow the prescribed review time or are there deviations? How do NBs ensure a reasonable review time?
The market will regulate itself, but an upper bound is necessary.

How can knowledge gained from first review be applied to subsequent reviews?
For complex products, NBs have guidelines. All of this assumes a good quality submission! NBs provide pointers, not tell manufacturers what to do.

What impacts review? NBs are changing opinions over time. How do we align and avoid repeated requests?
Some NBs have internal calibration meetings. This starts with good quality feedback from manufacturers. Some are intimidated from pushing back on NBs. Ask NBs to provide a specific rationale for why a finding is a non-conformity. Continue to challenge. The communication between the Scheme Manager and subject matter experts is usually very good. NBs offer mtgs when a non-conformity is not understood. More manufacturers are taking advantage of this. Many manufacturers are afraid to speak to their NB. This is sometimes due to cost considerations as some NBs may charge for this. However, this process is good for both NBs and manufacturers as it can save time and resources down the road- escalate, appeal, discuss!

Does the Code of Conduct include the Clinical Evaluation Consultation Procedure (CECP)?
CECP is still evolving. It is important to build NB experience with CECP, and how it is applied to specific products. It is still in a pilot phase and too premature to establish standardized practices right now. Topics where challenges are noted will be handled through a rolling Q&A.

How can NBs publicly communicate their positions?
Suggest manufacturers put findings in 3 buckets (1-agree and know how to answer, 2-agree but don't know how to answer, 3-disagree with finding). NBs should encourage reviewers to put their egos and "need to know and be comfortable" aside and focus on the non-conformities only.

Does the Code of Conduct account for smaller NBs who may have resource constraints?
Maybe to the extent of what is charged for training, etc.; otherwise, there can be no distinction. Smaller NBs, however, may have different processes for how they achieve the Code of Conduct. Others are more niche in their expertise/ product focus.

How do NBs ensure compliance with the Code of Conduct in accordance with the timeline for implementation? *This is not difficult.*

How is the Code of Conduct updated to address new technologies, such as digital technologies/ innovative devices?
We are working on innovative pathways-started with Orphan devices- can now issue certificates with conditions- this is something new. Need a committee or checklist/ consultation group/ TF?- There is work to do in this area. An example is the Innovative Devices Access Pathway (iDAP) pilot. It is important to be forward thinking and stay ahead of the curve- ensuring sufficient capacity. This starts with NB and industry- future guidance across NBs will develop over time.

STRUCTURED DIALOGUE
Balazs Bozsik, SGS

Historically, Structured Dialogue was connected to the time of the Directives, when it was recognized that increased dialogue with manufacturers would reduce overall time to certification. It is not meant to be advice/consultation. During joint assessment, communications with manufacturers started to be questioned. It was felt to not be appropriate before a file is opened and led to NBs not feeling comfortable with their discussions with industry. Some

manufacturers misused the feedback and went shopping until they found a NB who agreed with their strategy. Manufacturers must choose a single NB and cannot apply to multiple NBs at the same time. Some companies feel there are not enough opportunities to have discussion with their NB. Annex 1.2.9 of Annex VII of MDR established a starting point for Structured Discussions. This is not analogous to the FDA pre-submission process. MDCG encourages Structured Dialogue between NBs and manufacturers, although there are always gray areas between what constitutes discussion vs. consultation. **NBs can discuss project plans, submission requirements, requirements for reporting a change, applicability of guidance, standards and common specifications, costs and timeline, for example, but cannot complete gap analyses, check for MDR/IVDR readiness (a.k.a. pre-audit), review mock files or clinical development strategy, provide technical solutions or explain how the manufacturer should meet specific regulatory requirements.** For example, the NB will not decide on the classification rule/resulting class and UDI structure, create an application attachment, find the manufacturer's supply chain, brainstorm how the manufacturer can/should meet certain requirements, explain how the manufacturer should change documentation, etc.

STRUCTURED DIALOGUE PANEL SESSION
Moderator: Bassil Akra, PhD, AKRA Team GmbH
Panel Members: Marie Abdallah, GMED, Ehab Amen, GMED, Andrea Pietsch, PhD, TÜV SÜD, Ibim Tariah, PhD, SGS, Balazs Bozsik, SGS, Purvi Patel, PhD, Team NB

What is the process for getting a Structured Dialogue? Can it be requested prior to an application?
This usually happens organically, as needed.

Should these discussions be limited to a few targeted topics, with common SMEs?
Not necessarily. Recommend focusing on key and most pressing questions first. SMEs now have greater bandwidth for Structured Dialogue under MDR (vs MDD).

For small changes in material- will an equivalence approach be acceptable w/o clinical data? Can NBs provide this feedback, even if paid for?
No- clinical and regulatory strategy is outside of scope.

How binding are decisions? How are they documented/ formalized?
There may be different opinions among NBs. The Code of Conduct addresses Structured Dialogue. The feedback should be binding. If applications are submitted much later, feedback may, however, no longer be applicable.

How formalized is the process? What is the process for applying and lead times?
Structured Dialogue is considered to be a clarification of requirements, regulations, QMS requirements, etc. (pre-application). It cannot be a "recipe for how to do it." This is consultancy. It is important for manufacturers to appropriately structure their discussions with NBs- outline specific understanding and ask NB to confirm. This will build mutual trust (not NB-shopping). NBs have been burned in the past where advice has been taken out of context. This leads to need for disclaimers. Suggest establishing early on the appropriate NB contacts to

ensure you are contacting the right people for the right discussions. NB reviewers are also permitted to contact the manufacturers directly.

Can a manufacturer request a different reviewer?
Yes- This can result in follow-on actions by NB if similar trends are identified.

Based on experience, it has become expected for manufacturers to seek FDA pre-submissions for 510(k)s unless requirements are well established. Do you anticipate that Structured Dialogues will similarly evolve?
Right now, the process is voluntary. Time will tell with further experience. Depends on value-add. Could be a benefit to a company in order to obtain outside validation of requirements for management purposes. Need to balance need for Structured Dialogue with impact to internal NB resources. Need to make these discussions more transparent, particularly for product-specific issues. This would be a benefit to all.

Are there differences in requirements between NBs for Class I devices?
There can be different interpretations for Class I s,m,r devices.

EXPERT NOTIFIED BODY PANEL ON ORTHOPEDIC SUBMISSIONS: WHAT'S WORKING AND WHAT IS NOT
Moderator: Bassil Akra, PhD, AKRA Team GmbH
Panel Members: Chris Brodrick, GMED, Andrea Pietsch, PhD, TÜV SÜD, Ibim Tariah, PhD, SGS, Balazs Bozsik, SGS, Daniel Hoehn, BSI Group

On a positive note, we have come a long way from the early days. **Submissions have improved significantly, we are learning together, internal processes have been established, and checklists and guidance documents have been developed. We have also seen improvements in GSPRs, implant cards, labeling, legacy devices (PMCF studies have been proactively done), educational efforts and best practices.** It is suggested that manufacturers identify shared documentation across files in advance- avoids duplicative review efforts. Despite improvements, **there remains continued challenges, particularly in the areas of Clinical and Risk Management.**

OSMA Meeting F/U Opportunity- NBs should share common deficiencies with manufacturers with sufficient detail for manufacturers to set expectations and avoid repeated deficiencies of the same type. Manufacturers could also compile and share common non-conformities that could be shared with NBs.

Article 61.10 route for instruments- many manufacturers are struggling with this. Team NB is working on this now to provide future guidance and clarification.

How are transitions managed (e.g., change in reviewer, reviewer out on leave)? Are there processes in place?
A specific transition plan is required for this. Need access to previous documentation. Challenges- loss of history, contacts, relationships, etc. Recommend onboarding process/training with new reviewer- could help to expedite reviews. Interaction is encouraged.

What is not going well?
Feasibility testing, compatibility of system components/ clinical data, ISO 10993- shift to chemical characterization, requiring many rationales, basic UDI grouping, risk management file

RENEWALS AND TRANSFERS
Andrea Pietsch, PhD, TÜV SÜD, Daniel Hoehn, BSI Group

There is a 5-year validity of certificates. Renewals are required by MDR, MDCG and UKCA. There is both planned surveillance (QMS, Microbiological, Technical, UAV) and unplanned surveillance (Vigilance and Substantial Change Review). The NBs strive for a balanced approach between no review and unplanned review. Reminders are sent at 12 and 9 months prior to certificate expiry. Phases of the renewal process include the client confirming the request to renew, receipt of the renewal, recommendations/decision making, certificate renewal, and submission of changes. **Changes should be submitted separately from renewals. Consultations with the Competent Authority may be required (ensure you submit documentation on time). A certificate can be re-issued up to 3 months in advance and maintain the prior expiration date + 5 years.**

What is reviewed?
QMS certificates, list of changes, risk management, compliance updates (GSPR, standards, etc.), PMS+PSUR+SS(C)Ps and clinical oversight with clinical review

Be proactive- do not let certificates expire! Be aware of any NCs, follow-up actions, change notifications, change in FTE #s, etc. **The Legal Manufacturer must provide approval to conduct the renewal and confirm what certificates/ devices are not to review, complete relevant forms requested by the NB, provide a list of all products currently CE marked, ISO 13485 certification for all critical subcontractors and critical suppliers, summary of vigilance incidents over last 5 years, EU Representative, and changes in the device design, PMS, state of the art, clinical data, etc.**

What happens if a manufacturer comes in after 5 years without any new clinical data?
General consensus- you should try to collect data as per PMCF/ PMS plan.

What are some scenarios for transferring to a new NB/ change in certification body?
In some cases, a particular NB may not have the expertise or designation for the products in question. There are different types of transfers: **Transfer of certification due to (EN) ISO 13485** (*change in certification body (CB) for the scope of certification assessment procedure and the related transfer of certificates from another CB into the responsibility of a new CB according to (EN) ISO 13485*); **Transfer of certification due to MDR** (*The change of the NB for the scope of conformity assessment procedure and the related transfer of certificates from another NB into the responsibility of a new NB according to MDR*); **Voluntary transfer** (*The manufacturer parts with the outgoing NB/ issuing CB although the outgoing NB/ issuing CB can continue to provide its service or the outgoing NB/ issuing CB parts with the manufacturer although he continues to produce the same devices the outgoing NB/ issuing CB has certified (e.g., dissolution of service agreement).)* and **Enforced/ involuntary (unintended) transfer** (*e.g., because of conflicts*

between client and outgoing NB/ issuing CA resulting in withdrawal of certification, refusing the execution of any surveillance by outgoing NB/ issuing CA).

Renewals and Transfers- Summary and Key Takeaways
Transferring to a NB under MDR is a complex but manageable process if done with proper planning; For high-risk devices such as orthopedic implants, early engagement with a designated NB/CB and thorough documentation review are critical to avoid regulatory gaps during the transfer process; A full conformity assessment according to Article 52 MDR is not necessary as long as sufficient information with respect to the conformity activities performed by the outgoing NB is available; A transfer of certification after expiry/ loss of validity of the certificate to be transferred is not possible- instead of transfer an initial certification must be performed; ISO 13485- no transfer agreement is needed; and Post-transfer activities: Update all relevant documentation (e.g., QMS, declarations of conformity, labeling) to reflect the new NB details (name and number) and prepare for any follow-up audits required by the new NB.

Cannot transfer in the middle of an application review based on disagreement of NCs. The new NB will ask to see documentation of other NB's feedback. There needs to be a formal transfer of the application (between NBs). Plan and allow sufficient time for transfer!

WHAT CHANGES CAN WE EXPECT TO THE MDR IN 2025
Erik Vollebregt, Axon Lawyers

In the beginning, there was political hype driving the need for change. MDR and IVDR overshot the mark as a result. In the EU, silos largely correspond to Commission organization. The highly decentralized model of devices is not appropriate anymore and does not support EU and national health policy. 50% of manufacturers are not launching in Europe first anymore due to costs, duration and general unpredictability of market access process. Some devices are not brought to Europe at all due to portfolio reductions and discontinuations. Health institutions are starting to experience shortages of specific devices, such as orphan and niche devices. There is a desire to integrate market access with health technology assessment (HTA)- reimbursement. The current approach is to legislate by guidance via MDCG- this is unconstitutional. Manufacturers are encouraged to invest in active participation in development of regulation and guidance, educate upstream suppliers and service providers, and "unsilo" design and development within the company. Start with phase-in of regulatory requirements before they apply (e.g., batteries, AI) and create strong links between legal and regulatory functions to implement new processes and manage risks. Current areas for reform include recertification, innovation friendly pathways, international reliance, cooperation and harmonization, reduced bureaucracy/standardization of documentation and centralization/governance. Anticipated 2025 changes include implementation of specifics under MDR and IVDR (e.g., eIFU regulation), phased in horizontal legislation (Batteries Regulation, AI Act, Product Liability Directive), and data, cybersecurity and AI legislation.

FUTURE LEGISLATION PANEL DISCUSSION
Moderator: Bassil Akra, PhD, AKRA Team GmbH
Panel Members: Marie Abdallah, GMED, Ehab Amen, GMED, Andrea Pietsch, PhD, TÜV SÜD, Ibim Tariah, PhD, SGS, Balazs Bozsik, SGS, Purvi Patel, PhD, Team NB

NBs are also aligned with the need for change. We need patient-oriented solutions and the EU is looking for solutions and measures. There is a need for central governance and more direction from the Commission and for member states to align and make firm decisions. There is also the need for a special pathway for innovative devices. MDSAP is a great example of international reliance/ mutual recognition. There is need for more standardization, EU-level harmonization of authorization of NBs and recognition of expertise among NBs.

For AI/ML technology, there are legal and data privacy barriers applicable to technical documentation.

Wasteful work should be avoided- How much sampling can be given up without sacrificing the quality of the work? Can a "recipe" approach be taken without asking manufacturers to reinvent the wheel each time? Also true for NBs- Could a more standardized approach/ templates be used? We need harmonization throughout the entire system (not just NBs) and to take a more systematic approach, not just small "fixes." Member states are not promoting harmonization and elimination of redundant work. There is EU receptivity to MDSAP and MDSRP- Areas of potential opportunity!

As a result of current regulations, are we seeing product shortages in the EU that are directly impacting the patient?
We will likely be seeing this soon- not immediately because of delays in implementation, but there is currently no way of knowing- this is not tracked. There is no evidence that the regulations have favorably impacted patient safety (original intent).

There are many opportunities for OSMA to engage this year and help people to understand how orthopedic devices can be regulated in a better way.