### Desk Assessment of Vector Control Product Manufacturer

#### Part 1: General information

<table>
<thead>
<tr>
<th><strong>Company information</strong></th>
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<tbody>
<tr>
<td><strong>Name of manufacturer</strong></td>
<td>Onomichi Kumika Industry Co. Ltd</td>
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<tr>
<td><strong>Corporate address of manufacturer</strong></td>
<td>Onomichi Kumika Industry Co. Ltd 160, Chojabara 2-chome, Onomichi, Hiroshima 722-0221 Japan</td>
</tr>
</tbody>
</table>

#### Manufacturing site(s) under assessment

| **Name & address of inspected manufacturing site(s) if different from that given above** | Same as above |
| **Unit/Block/Workshop** | Not applicable |

#### Desk assessment details

| **Dates of review** | 15-22 February 2023 |
| **Products covered by this desk assessment** | Vectron T500 - P-03226 |
| **List of documents submitted** | 1) Site Master File  
2) Site floor plans  
3) Full address of manufacturing site  
4) Quality Manual – only cover page in English.  
5) Quality Manual – In Japanese  
6) Staff Organogram  
7) List of current Quality Management Procedures  
8) Complaint handling, vigilance and recalls procedure  
9) Control of non-conforming products procedure  
10) Procedure for control of changes/change notifications  
11) Supplier evaluation  
12) Risk Management  
14) Audit planning  
15) QMS certification of conformity  
16) Renewal audit report Issued 22 September 2022  
17) Minor defect report and CAPA 2018  
18) Minor defect report and CAPA 2022  
19) List of products and formulation types at this site |
20) Name and contact details of the responsible person at the manufacturing facility
21) Process flow chart
22) Most recent Management review minutes
23) Completed batch record of WHO product
24) Master batch record for the WHO product of interest
25) List of recall/returns at Onomichi Kumika

<table>
<thead>
<tr>
<th>Abbreviations</th>
<th>Meaning</th>
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<tbody>
<tr>
<td>NC</td>
<td>Non-conformity</td>
</tr>
<tr>
<td>NCR</td>
<td>Non-conformity Report</td>
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<tr>
<td>OOS</td>
<td>Out-of-specification</td>
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<tr>
<td>QC</td>
<td>Quality Control</td>
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<tr>
<td>QMS</td>
<td>Quality Management System</td>
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**Part 2**

<table>
<thead>
<tr>
<th>Name of ISO certification body</th>
<th>Dates of Audit</th>
<th>Report Issued - 22 September 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan Chemical Quality Assurance Ltd (JCQA)</td>
<td>Type of Audit</td>
<td>Renewal Audit (Recertification audit)</td>
</tr>
<tr>
<td>Inspected areas/documents</td>
<td>Change of QMS, facilities, Overview of internal and external challenges, needs of interested parties, overview of interview with Top Management, organizational strength to develop the commitment of Top Management, determination of risks and opportunities, monitoring measuring and evaluating key performance indicators, records of complaints and internal nonconformities, internal audits, management review</td>
<td></td>
</tr>
</tbody>
</table>

| Product covered | Product names redacted. |

<table>
<thead>
<tr>
<th>Date of Audit</th>
<th>Report Issued - 20 July 2020.</th>
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<tbody>
<tr>
<td>Type of Audit</td>
<td>Surveillance audit</td>
</tr>
<tr>
<td>Inspected areas/documents</td>
<td>Overview of internal and external challenges, needs of interested parties, information from Top Management or QC manager, organizational strength to develop the commitment of Top Management, determination of risks</td>
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Part 3

Summary of the last WHO inspection

The site has not been inspected by WHO before.

Part 4

Summary of the assessment of supporting documentation

1. Quality Manual:
Only the cover page was translated to English was provided.

2. List of current quality management procedures:
A list of the current quality management procedures was provided.

3. Standard operating procedures for:
   i. Complaint handling, vigilance and recalls:
The procedure titled ‘Complaint handling, Vigilance and Recalls’ was reviewed. The procedure described the receipt and handling of complaints. The procedure included root cause investigation, corrective and preventive actions and verification of preventive measures.

   ii. Control of nonconforming goods/processes:
The translated procedure for control of nonconforming products/processes described the measures in place for handling nonconforming products and defined the persons responsible for handling the nonconformities. Records of nonconformities were to be maintained and identified as such. The procedure also allowed for impact assessment, root cause investigation, and CAPA.

   iii. Change control/change notifications (product and processes):
A procedure for change control described the management of changes related production equipment, manufacturing methods, prices, quality of raw materials, changes to transaction conditions. The impact of changes was reviewed.

   iv. Risk management:
An excerpt of the quality manual describing risk management was provided. Each manager determined the risks in their respective departments. Risk and opportunities were reviewed twice a year. The Quality Control Committee discussed the appropriateness of risks and opportunities.
v. Supplier evaluation and control, verification of purchased product:
The procedure described criteria for the selection of supplier of production equipment, measuring equipment, storage/transport consignment, external calibration, maintenance and packaging materials, measuring instruments, reagents, external analysis, external calibration, maintenance, and raw materials. Records were maintained.

4. Site Master File (SMF) and site floor plan
The Site Master File provided an overview of the quality management system, personnel, premises, equipment, documentation, production, quality control complaints distribution, product defects and internal audits. The layout of the buildings on site was provided.

5. Quality management system certificate(s) and scope of certification: (e.g., ISO 13485/ISO 9001):
A valid ISO 9001:2015 certificate was provided.

6. List of notifications of upcoming inspections by the regulatory authorities or ISO 9001:2015 certification bodies in the next 6 months:
No inspections were planned in the next 6 months.

7. Process flowchart including in-process control points:
The process flow chart for the manufacture of Vectron T500 was provided.

8. List of all the products and formulation types manufactured at this site:
A list of products manufactured on site was provided.

9. Most recent management review report/minutes:
The most recent management review minutes were reviewed.

10. Master batch manufacturing, and/or packaging records of the WHO product of interest:
Templates of the manufacturing records were provided and reviewed.

11. Completed batch manufacturing and/or packaging records:
Batch manufacturing and packaging records were provided and reviewed.

12. List of any recalls/returns:
Manufacturer declared that no recalls had been performed.

13. List of equipment that is shared and measures in place to ensure that this sharing of equipment is managed appropriately:
No information was provided.

14. Name and address of sites to which any related activities are outsourced:
No information was provided.

15. Additional documents submitted:
None.
Part 5  Desk assessment conclusion

Based on the inspection by the Japan Chemical Quality Assurance Ltd (JCQA) and on the QMS evidence received and reviewed; it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site Onomichi Kumika Industry Co. Ltd located at 160, Chojabaru 2-chome, Onomichi, Hiroshima 722-0221 Japan is considered to be operating at an acceptable level of compliance with ISO 9001:2015 standard and WHO guidelines as per Overview of the WHO Prequalification Assessment of Vector Control Products, June 2021. This compliance status shall be valid until 8th November 2025 or when another inspection is conducted by WHO or by a reliable certification body.

Part 6  List of Standards and Guidelines referenced in the inspection report

   https://www.iso.org


3. Overview of the WHO Prequalification Assessment of Vector Control Products, June 2021