

POSITION DESCRIPTION – WHS & QA Compliance Officer

POSITION TITLE:	WHS/QA Manager
DEPARTMENT:	Regulatory, Facilities, Safety & Security
LOCATION:	Head Office-Sydney
AWARD:	Non Award
ISSUED:	TBA

REPORTS TO:	Director - Facilities, Safety, Security & Regulatory
FUNCTIONAL RELATIONSHIPS WITH:	<p>Provides Guidance to:</p> <ul style="list-style-type: none"> • Director - Facilities, Safety, Security & Regulatory • Regulatory Affairs (ANZ and HSI) • General Managers • Department Heads • Safety Committees <p>Receives Guidance From:</p> <ul style="list-style-type: none"> • Director - Facilities, Safety, Security & Regulatory • VP Regulatory & Legal Affairs • General Managers • Department Heads • Safety Committees
DIRECT REPORTS INCLUDE:	<ul style="list-style-type: none"> • NIL
SIGNIFICANT CONTACT WITH:	<ul style="list-style-type: none"> • Various State and Federal Government Authorities • VP Regulatory & Legal Affairs • BSI - our Notified Body • HR Departments
FINANCIAL DELEGATIONS:	Consultancy fees

POSITION OVERVIEW

Support and help develop, maintain and oversee a consistent Work, Health, Safety, Security and Quality Management and compliance culture across Henry Schein's existing Dental, Animal Health and other Henry Schein subsidiaries and companies in ANZ. Ensures all necessary company licences for facilities, import, export and others as required are tracked and maintained. Responsible for reviewing and maintaining or developing and publishing, with support of department heads, appropriate policies and standards. Induct departments and TSMs on those policies and standards. Monitor and report on compliance of Regulatory/QA and WHS processes. Provides reporting on any government agency audits or inspections and manages any resulting actions. Manage and report on incidents and non conformances, assist with identifying corrective and preventive actions and coordinate associated action plans. Provides advice and support to various companies and departments on WHS and Regulatory/QA issues. Other projects within position scope as needed and or directed and any other tasks as assigned from time to time.

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JOB SPECIFICATION

WHS Responsibilities

1. This role will lead health and safety initiatives and development of a Work Health and Safety (WHS) culture for Henry Schein in Australasia.
2. Coordinate WHS activities across the different companies and contribute to the development and implementation of plans regarding key health and safety strategies. Recommend operational and business requirements to support those strategic objectives for continuous improvement, meeting legislation and or code requirements and supporting best practice principles.
3. Advise management and the heads of department about responsibilities under the Act and the overall state of occupational health and safety at the workplace including monthly management reporting on the status of the WHS programme.
4. Provide training and guidance for work health and safety committees and coordinate their reporting requirements to ensure they have the skills to identify risks, operate and report effectively. Prepare and deliver appropriate training and education materials including induction materials and toolbox talks.
5. Review committee activities to ensure hazards and unsafe workplace conditions and work practices have been identified, reported and are being acted on. Monitor corrective activities to ensure risks are eliminated, isolated or minimised and maintains the various registers and reporting requirements of the WHS Management System.
6. Supervising the investigation of accidents, incidents, near misses and unsafe working conditions including reporting of identified hazards and appropriate risk control measures to the heads of department. Review the circumstances of any work injury, illness and dangerous events, identify any corrective action and request any additional resources or assistance required to undertake this corrective action. Coordinate with Director Facilities, Safety, Security & Regulatory to ensure incidents that need reporting to State authorities are done so and subsequently liaise with and comply with any associated audits and investigations. Advise on the potential requirement for legal support.
7. Works with the Director Facilities, Safety, Security & Regulatory to develop, implement and maintain a WHS Safety Management System aligned with current AS/NZS 4801 standards and ensure ongoing compliance and continuous improvement. This will require developing health and safety policies and procedures.
8. Assist in compliance processes related to visitors and any usage of contractors.
9. Ensure companies/facilities have adequate fire protection equipment, that they have current validation and training of wardens and staff is ongoing. Coordinate the activities of the First Aiders to ensure there is adequate coverage and their training is appropriate and current. Ensure there are first aid kits and other equipment available, that they are complete and current including that personal protective equipment where required has been provided, staff trained and or instructed on the usage and that they comply.
10. Ensure that any dangerous goods or materials are correctly stored and the appropriate MSDS are available and staff trained in handling the goods and any potential spills.
11. Assist with internal and external audits to ensure compliance with the WHS Safety Management System and relevant legislation.

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Quality/Regulatory Compliance

1. Support and help develop a Quality Management culture across Henry Schein operations. Ensure all company operations are meeting or exceeding Global Henry Schein standards, with Henry Schein Regulatory Affairs support. Ensure ongoing compliance with applicable regulations. Coordinate compliance activities across the different companies and contribute to the development and implementation of plans regarding key compliance strategies and continuous improvement.
2. Attend management meetings to promote RA/QA standards and support strategic goals including preparing monthly management reporting on the status of RA/QA activities. Advise management and department heads about compliance responsibilities, and institute and maintain an effective compliance communication program for ANZ, including promoting the understanding of new and existing compliance issues and related policies and procedures.
3. Manage the development, maintenance and revision of policies and procedures for the Management Systems and SOPs and their related activities to ensure they continue to be relevant and provide effective management, customer satisfaction and ensure the meeting of QA requirements. (ISO 9001 and ISO 13485).
4. Manage the Quality Management software, distinct from the content, so that it operates effectively, keeps the appropriate staff informed and provides effective output to corporate intranet or equivalent of the policies and procedures. Ensure department heads and TSMs are trained in how best to use the software to meet their own objectives and maintain quality standards.
5. Review policies and procedures applied locally to ensure they meet corporate requirements through One Company One System (1C1S). Work with department heads to manage any variations to requirements to ensure they are addressed by the appropriate departments. Ensure appropriate department heads are aware of their 1C1S requirements and have signed off and any gaps or variations have been identified, reported and, if necessary, assist and or coordinate corrective processes to ensure they meet requirements. Maintain corporate database for 1C1S.
6. Monitor and report on performance of compliance through regular facility and department audits on a continuing basis, ensure that any compliance issues/concerns are being appropriately evaluated, investigated and resolved as well as looking for opportunities to improve effectiveness. Maintain and oversee a system for uniform handling of non-conformances. Identify potential areas of compliance vulnerability and risk; work with department heads and provide general guidance on corrective action plans for resolution and how to avoid or deal with similar situations in the future.
7. Work with HR and others as appropriate to develop an effective compliance training program, including appropriate introductory training for new employees as well as ongoing training for all employees and managers.
8. Assist in conducting supplier and due diligence audits and assist with due diligence in ANZ. Ensure timely resolution of any non-compliance findings. Review and monitor policies and procedures applied locally for dealing with external suppliers and contractors; ensure their products/services meet company quality standards.
9. Manage and report on any inspections and audits from external authorities on products or facilities including TGA post market activities. Ensure appropriate and timely resolution of any issues. Maintain positive relationships with government authorities and other regulatory authorities and represent the company in matters before regulatory and industry standards agencies to advance company interests. Ensures proper reporting of any events to Henry Schein Inc. and appropriate agencies as required.
10. Obtain and coordinate maintenance of all relevant company licences for all ANZ facilities as well as

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export and import permits and others as required. Maintain the data on corporate database so requirements can be monitored; develop reporting requirements to ensure the database is being maintained and remains current. Assist in maintaining the Regulatory Affairs database on product data and Safety Data Sheets including maintaining SDS (MSDS) information if required and ensure the data is to Australian requirements. Coordinate the process for obtaining these if not immediately available by liaising with the Brand Managers and the Suppliers.

11. Monitor any product complaints and ensure they are managed. Document and report on complaints or product quality issues on Henry Schein Brand products. Ensure any adverse events are immediately highlighted and responses coordinated.
12. Ensure appropriate processes for customer qualification verifications, hazardous materials handling, and product integrity maintenance.
13. Develop a high level of Regulatory intelligence e.g. on existing and developing regulations in Australia and New Zealand.
14. Carry out research with the TGA, Medsafe, Australian Pesticides and Veterinarian Medicines Authority (APVMA) or Agricultural Compounds & Veterinary Medicines (ACVM) in New Zealand and other authorities for information regarding product registrations, company data and warnings. Provide back up on basic and low risk TGA and Medsafe registrations.
15. Assist in research on suppliers as part of the DD process for exclusive arrangements.

POSITION DEMANDS

- NIL

QUALIFICATIONS & ATTRIBUTES

EXPERIENCE	<ul style="list-style-type: none"> • This role requires a proven commitment to quality management systems backed up with a proven technical WHS and QA knowledge base (ISO 9001 and ISO 4801) and an exposure to meeting State and Federal regulatory requirements. • Experience in developing and implementing a Quality Management System (QMS) to meet all corporate and regulatory requirements. • Experience in processes to import and register products well considered. • Experience with TGA, controlled substances, pharmaceuticals and medical devices well considered. • Demonstrate experience of coaching and or running training programs. • Ability to manage senior staff and Government departments. • Ability to influence and motivate others. • Exposure to distribution and warehouse operations and licence requirements an advantage.
EDUCATION	<ul style="list-style-type: none"> • This role has a level of skill commensurate with a bachelor degree preferably in Business Management, or a tertiary degree preferably in a scientific/technical discipline or a related field, or at least five years work experience in WHS and Quality Assurance Management may substitute. • Must be fluent in written and spoken English.
SPECIALISED KNOWLEDGE AND SKILLS	<ul style="list-style-type: none"> • Audit qualifications (RABQSA) in WHS and QA an advantage. • Process Improvement experience and ability to analyse information.

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PERSONAL ATTRIBUTES	<ul style="list-style-type: none">• Dealing with government regulatory bodies.• Analytical and critical thinking skills.• High attention to detail.• Ability to self manage and meet deadlines.• Business acumen.• Excellent communication skills especially written skills.
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OTHER REQUIREMENTS OF THIS POSITION INCLUDE

CODE OF CONDUCT & ORGANISATIONAL VALUES

Henry Schein and its Team Schein Members (TSMs) are mutually responsible for the success of the business. The company promises to create an environment in which all TSMs can realise their full potential. In return, all TSMs are expected to make contributions that positively impact our customers, our shareholders, our suppliers, our community and each other.

This includes:

- conduct to the highest degree of ethics and integrity
- creative thinking and openness to new challenges
- appreciating diversity in the workplace and treating everyone with courtesy and respect
- effective communication, which is open and honest
- modelling best practice and leadership

Company values and standards are detailed in the "Values of Team Schein" and Worldwide Business Standards Booklet.